



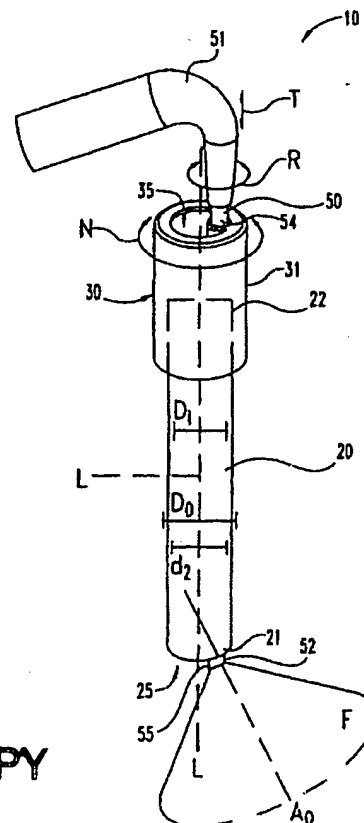
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: <b>PCT/US97/04004</b> (22) International Filing Date: 14 March 1997 (14.03.97) (30) Priority Data: 08/620,933      22 March 1996 (22.03.96)      US 08/736,626      24 October 1996 (24.10.96)      US (71) Applicant: <b>DANEK MEDICAL, INC. [US/US]; 1800 Pyramid Place, Memphis, TN 38132 (US).</b> (72) Inventors: <b>FOLEY, Kevin, Thomas; 2877 Keasler Circle West, Germantown, TN 38139 (US). SMITH, Maurice, Mell; 9285 Oak Knoll Cove, Cordova, TN 38018 (US). CLAYTON, John, B.; 9577 Gotten Way, Germantown, TN 38139 (US). MOCTEZUMA, Joseph; 6445 Birch Mill Cove, Bartlett, TN 38135 (US).</b> (74) Agents: <b>BECK, Michael, D. et al.; Woodard, Emhardt, Naughton, Moriarty &amp; McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).</b>			(81) Designated States: <b>AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</b>  Published <i>Without international search report and to be republished upon receipt of that report.</i>

(54) Title: **DEVICES AND METHODS FOR PERCUTANEOUS SURGERY**

## (57) Abstract

Devices and methods for performing percutaneous surgery under direct visualization and through a single cannula are shown. A device (10) includes an elongated cannula (20) having a first inner diameter ( $D_1$ ) and an outer diameter ( $D_0$ ) sized for percutaneous introduction. The cannula (20) defines a working channel (25) between its ends (21, 22) which has a second diameter ( $D_2$ ) equal to the diameter ( $D_1$ ) of the cannula sized for receiving a tool therethrough. An elongated viewing element (50) is engageable to the cannula (20) adjacent the working channel (25), preferably by a fixture (30, 170). The fixture (30, 170) includes a housing/body (31, 171) attachable to the proximal end (22) of the cannula (20). The housing (31) defines an optics bore (60, 180) to support a viewing element (50) for translation and rotation relative to the cannula (20) so that the longitudinal axis of the optics bore (60, 180) will translate parallel to and rotate about the longitudinal axis of the working channel (25). Methods are also provided for performing surgeries percutaneously with direct visualization and without the requirement for a fluid-maintained workspace.



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## DEVICES AND METHODS FOR PERCUTANEOUS SURGERY

## RELATED APPLICATIONS

This application is a continuation-in-part of U.S. application no. 08/620,933 filed on March 22, 1996 entitled "Devices and Methods for Percutaneous Surgery" by the same  
5 inventors.

The present invention relates to devices, instruments and methods for performing percutaneous surgeries, particularly at locations deep within the body. One specific application of the invention concern devices,  
10 instruments and techniques for percutaneous, minimally invasive spinal surgery. In another aspect of the invention, the percutaneous surgery is performed under direct vision at any location in the body.

Traditional surgical procedures for pathologies located  
15 deep within the body can cause significant trauma to the intervening tissues. These open procedures often require a long incision, extensive muscle stripping, prolonged retraction of tissues, denervation and devascularization of tissue. Most of these surgeries require a recovery room  
20 time of several hours and several weeks of post-operative recovery time due to the use of general anesthesia and the destruction of tissue during the surgical procedure. In some cases, these invasive procedures lead to permanent scarring and pain that can be more severe than the pain  
25 leading to the surgical intervention.

Minimally invasive alternatives such as arthroscopic techniques reduce pain, post-operative recovery time and the destruction of healthy tissue. Orthopedic surgical patients

-2-

have particularly benefited from minimally invasive surgical techniques. The site of pathology is accessed through portals rather than through a significant incision thus preserving the integrity of the intervening tissues. These  
5 minimally invasive techniques also often require only local anesthesia. The avoidance of general anesthesia reduces post-operative recovery time and the risk of complications.

Minimally invasive surgical techniques are particularly desirable for spinal and neurosurgical applications because  
10 of the need for access to locations deep within the body and the danger of damage to vital intervening tissues. For example, a common open procedure for disc herniation, laminectomy followed by discectomy requires stripping or dissection of the major muscles of the back to expose the  
15 spine. In a posterior approach, tissue including spinal nerves and blood vessels around the dural sac, ligaments and muscle must be retracted to clear a channel from the skin to the disc. These procedures normally take at least one-two hours to perform under general anesthesia and require  
20 post-operative recovery periods of at least several weeks. In addition to the long recovery time, the destruction of tissue is a major disadvantage of open spinal procedures. This aspect of open procedures is even more invasive when the discectomy is accompanied by fusion of the adjacent  
25 vertebrae. Many patients are reluctant to seek surgery as a solution to pain caused by herniated discs and other spinal conditions because of the severe pain sometimes associated with the muscle dissection.

In order to reduce the post-operative recovery time and  
30 pain associated with spinal and other procedures, micro-surgical techniques have been developed. For example, in micro-surgical discectomies, the disc is accessed by cutting a channel from the surface of the patient's back to

-3-

the disc through a small incision. An operating microscope or loupe is used to visualize the surgical field. Small diameter micro-surgical instruments are passed through the small incision and between two laminae and into the disc.

5 The intervening tissues are disrupted less because the incision is smaller. Although these micro-surgical procedures are less invasive, they still involve some of the same complications associated with open procedures, such as injury to the nerve root and dural sac, perineural scar

10 formation, reherniation at the surgical site and instability due to excess bone removal.

Other attempts have been made for minimally invasive procedures to correct symptomatic spinal conditions. One example is chemonucleolysis which involved the injection of

15 an enzyme into the disc to partially dissolve the nucleus to alleviate disc herniation. Unfortunately, the enzyme, chymopapain, has been plagued by concerns about both its effectiveness and complications such as severe spasms, post-operative pain and sensitivity reactions including

20 anaphylactic shock.

The development of percutaneous spinal procedures has yielded a major improvement in reducing recovery time and post-operative pain because they require minimal, if any, muscle dissection and they can be performed under local

25 anesthesia. For example, U.S. Patent No. 4,545,374 to Jacobson discloses a percutaneous lumbar discectomy using a lateral approach, preferably under fluoroscopic X-ray. This procedure is limited because it does not provide direct visualization of the discectomy site.

30 Other procedures have been developed which include arthroscopic visualization of the spine and intervening structures. U.S. Patent Nos. 4,573,448 and 5,395,317 to

-4-

Kambin disclose percutaneous decompression of herniated discs with a posterolateral approach. Fragments of the herniated disc are evacuated through a cannula positioned against the annulus. The '317 Kambin patent discloses a biportal procedure which involves percutaneously placing both a working cannula and a visualization cannula for an endoscope. This procedure allows simultaneous visualization and suction, irrigation and resection in disc procedures.

Unfortunately, disadvantages remain with these procedures and the accompanying tools because they are limited to a specific application or approach. For example, Jacobson, Kambin and other references require a lateral or a posterolateral approach for percutaneous discectomy. These approaches seek to avoid damage to soft tissue structures and the need for bone removal because it was thought to be impractical to cut and remove bone through a channel. However, these approaches do not address other spinal conditions which may require a mid-line approach, removal of bone or implants.

U.S. Pat. No. 5,439,464 to Shapiro discloses a method and instruments for performing arthroscopic spinal surgeries such as laminectomies and fusions with a mid-line or medial posterior approach using three cannulae. Each of the cannulae requires a separate incision. While Shapiro discloses an improvement over prior procedures which were limited to a posterolateral or lateral approach for disc work, Shapiro's procedure still suffers from many of the disadvantages of known prior percutaneous spinal surgery techniques and tools. One disadvantage of the Shapiro procedure is its requirement of a fluid working space. Another significant detriment is that the procedure requires multiple portals into the patient.

-5-

Fluid is required in these prior procedures to maintain the working space for proper function of optics fixed within a prior art cannula and inserted percutaneously. Irrigation, or the introduction of fluid into the working space, can often be logistically disadvantageous and even dangerous to the patient for several reasons. The introduction of fluid into the working space makes hemostasis more difficult and may damage surrounding tissue. Excess fluid may dangerously dilute the sodium concentration of the patient's blood supply which can cause seizures or worse. The fluid environment can also make drilling difficult due to cavitation. The requirement for a fluid environment generally increases expenses associated with the surgery and adds to the complexity of the surgery, due in part to the relatively high volume of fluid required.

A need has remained for devices and methods that provide for percutaneous minimally invasive surgery for all applications and approaches. A need has also remained for percutaneous methods and devices which do not require a fluid-filled working space, but that can be adapted to a fluid environment if necessary.

A significant need is present in this field for techniques and instruments that permit surgical procedures in the working space under direct vision. Procedures that reduce the number of entries into the patient are also highly desirable. The fields of spinal and neuro surgery have particularly sought devices and techniques that minimize the invasion into the patient and that are streamlined and concise in their application.

-6-

## SUMMARY OF THE INVENTION

Briefly describing one aspect of the invention, there is provided devices and method for performing percutaneous procedures under direct visualization, even at locations deep within a patient. In one embodiment, a device for use in percutaneous surgery includes an elongated cannula having a first inner dimension and an outer dimension sized for percutaneous introduction into a patient. The cannula further includes a distal working end and an opposite proximal end and defines a working channel between the ends having a second dimension which is equal to the first inner dimension. The working channel is sized to receive a tool therethrough. The device also includes a viewing element mounted inside the cannula adjacent the working channel. The viewing element has a first end connectable to a viewing apparatus and an opposite second end disposed adjacent the distal working end of the cannula. In some embodiments, the viewing element can be a fiber optic cable, a GRIN rod, a rod-lens device or a remote optics ("chip on a stick") device.

In another aspect, a fixture is provided for mounting the viewing element to the cannula. The fixture includes a housing attachable to the proximal end of the cannula. The housing defines a working channel opening therethrough in communication with the working channel. The working channel opening is sized to substantially correspond to the second dimension of the working channel. The housing also defines an optics bore adjacent the working channel opening. The optics bore is sized to receive the elongated viewing element therethrough.

In some embodiments, the fixture supports the viewing device for movement within the optics bore along the



-7-

longitudinal axis of the bore to extend or retract the lens relative to the distal working end of the cannula. In other embodiments, the fixture supports the viewing device for rotation within the optics bore about the longitudinal axis of the bore. In some embodiments, the housing is rotatable relative to the cannula so that the longitudinal axis of the optics bore is rotatable about the longitudinal axis of the working channel.

In one aspect of the invention, the working channel can be created by components other than a tubular cannula. For example, an expanding tissue dilator or tissue retractor is also contemplated. With this modification, the fixture would engage the dilator or retractor in its expanded condition.

In a further aspect of the invention, the optical viewing device is connected to a tissue retractor, such as a speculum. An apparatus of this type can be particularly useful in various applications such as transnasal transphenoidal surgery and pituitary procedures.

In a further aspect of the invention, the working channel maintained by the cannula or similar components can have a length calibrated so that the surgeon can maintain a tactile feel for instruments manipulated through the working channel. In spinal applications, certain beneficial aspects of the invention are attained by providing a cannula having a length slightly greater than the distance from the lamina of a vertebra to the surface of the patient's skin for posterior procedures. The viewing device is dimensioned relative to the cannula so that the viewing end of the device can project beyond the distal working end of the cannula or working channel to allow the surgeon to selectively survey the surgical site.

-8-

In accordance with one embodiment, the fixture includes at least one irrigation/aspiration port. Preferably, the port(s) can communicate with at least one irrigation/aspiration channel in the optical viewing device. In this manner, irrigation and/or aspiration can also be applied at the surgical site. When aspiration alone is applied, the port is connected to a vacuum or suction source. The aspiration will draw ambient air through the working channel, across the distal working space, and into the irrigation/aspiration channel of the viewing device. One benefit is that this ambient air aspiration eliminates smoke generated by various working tools and clears the optics lens of fog and debris.

In one embodiment, the fixture is mounted over and supported by the proximal end of the cannula.

In another embodiment, the fixture can be supported adjacent the proximal end of the cannula by a clamp engaging the outer surface of the cannula. In one specific embodiment, the clamp is a barrel clamp mechanism that is selectively operated by a lever arm and barrel cam. With this embodiment, the fixture itself can be translated along the length of the cannula to extend or retract the lens of the viewing device relative to the end of the working channel.

Novel tools are also provided which are insertable into the working channel of the cannula. A tissue retractor in one embodiment includes a body and an integral working tip configured to atraumatically displace tissue as the retractor is manipulated through tissue. The body has a convex surface configured to conform to the inner cylindrical surface of the cannula and an opposite concave

-9-

surface which does not obstruct the working channel or visualization of the working space. Cannulated tissue dilators are also provided which are insertable over a guidewire or another dilator as well as insertable into the working channel. In some embodiments, the tissue dilators include a tapered working end to displace tissue and a gripping portion having a number of circumferential grooves to enhance gripping and manipulation of the dilator.

According to the methods of this invention, spinal and other surgeries can be performed percutaneously with direct visualization without the requirement for a fluid-maintained working space. In another aspect of the inventive surgical techniques, all steps of a surgical procedure are conducted under direct vision through a single working channel cannula. An optical scope or viewing device is moved within the working channel and throughout the working space from a variety of angles and orientations to provide a clear view of the operative steps.

The techniques of the present invention also encompass passing multiple tools and instruments through the single working channel cannula and manipulating the instruments and tools within the working space. In one specific embodiment, a tissue retractor is provided that extends through the working channel without significantly reducing the dimensions of the channel.

It is an object of the invention to provide devices and methods for percutaneous spinal surgery for all applications and approaches. One advantage of this invention is that percutaneous procedures can be accomplished in a dry environment because a fluid working space is not required for the proper function of the optics. One benefit of this invention is that it provides instruments and methods which

-10-

reduce the cost, risk, pain and recovery time associated with surgery. These and other objects, advantages and features are accomplished according to the devices and methods of the present invention.

-11-

## DESCRIPTION OF THE FIGURES

FIG. 1 is a side elevational view of a device according to this invention.

FIG. 2 is a top elevational view of a fixture for supporting a viewing device within a cannula according to this invention.

FIG. 3 is a side cross-sectional view of the fixture shown in FIG. 2.

FIG. 4 is a side elevational view of a retractor according to one embodiment of this invention.

FIG. 4A is an end cross-sectional view of the retractor of FIG. 4 taken along lines A-A.

FIG. 5 is a top elevational view of the retractor shown in FIG. 4.

FIG. 6 is an end elevational view of the retractor shown in FIGS. 4 and 5.

FIG. 7 is a side elevational view of a retractor according to another embodiment of this invention..

FIG. 7A is an end cross-sectional view of the retractor of FIG. 7 taken along lines A-A.

FIG. 7B is an end cross-sectional view of the retractor of FIG. 7 taken along lines B-B.

FIG. 8 is a top elevational view of the retractor shown in FIG. 7.

-12-

FIG. 9 is a side elevational view of a dilator according to this invention.

FIG. 10 (a) -(i) depicts the steps of a method according to this invention.

5        FIG. 11 is a side cross-sectional view of a device according to one embodiment of this invention.

FIG. 12 is a side cross-sectional view of an aspiration cap as shown in FIG. 11.

10       FIG. 13 is a top perspective view of a device according to another embodiment of the present invention.

FIG. 14 is a side perspective view of a fixture for supporting a viewing device forming part of the device shown in FIG. 13.

15       FIG. 15 is a side elevational view of the device depicted in FIG. 13 with the device shown connected to optical equipment depicted in phantom lines.

FIG. 16 is a side elevational view of a scope body forming part of the fixture depicted in FIGS. 13 and 14.

20       FIG. 17 is a bottom elevational view of the scope body shown in FIG. 16.

FIG. 18 is a top elevational view of a lever arm forming part of a barrel clamp mechanism used with the fixture depicted in FIG. 14.

-13-

FIG. 19 is an end cross-sectional view of the lever arm shown in FIG. 18 taken along line 19-19 as viewed in the direction of the arrows.

5        FIG. 20 is a top elevational view of a barrel cam forming part of a barrel clamp mechanism incorporated into the fixture depicted in FIG. 14.

FIG. 21 is a side elevational view of the barrel cam shown in FIG. 20.

10       FIG. 22 is a bottom assembly view showing the assembly of the lever arm of FIGS. 18-19, the barrel cam of FIGS. 20-21 with the scope body shown in FIG. 14.

FIG. 23 is a side elevational view of a scope body as depicted in FIG. 14 connected to an aspiration circuit.

15       FIG. 24 is a cross-sectional view of a human patient at a lumbar vertebral level with a device according to one embodiment of the invention situated within the patient to define a working channel above the laminae of the vertebra.

FIG. 25 is a side elevational view of a tissue retractor incorporating an optical viewing device.

20       FIG. 26 is a top elevational view of the tissue retractor incorporating an optical viewing device as shown in FIG. 25.

-14-

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will  
5 nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated devices and described methods, and such further applications of the  
10 principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

The present invention provides instruments and methods for performing percutaneous surgery, including spinal  
15 applications such as laminotomy, laminectomy, foramenotomy, facetectomy or discectomy, with a single working channel endoscope. The present inventors have discovered that many percutaneous surgeries may be performed without a fluid workspace through the use of optics which move independently  
20 of the cannula. The present invention contemplates techniques and instruments that can be implemented with or without a fluid environment.

This invention also brings the advantages of percutaneous procedures to applications that previously  
25 required open surgery. One advantage is based upon the further discovery that bone work can be performed percutaneously through a large working channel. Another advantage is realized in the use of a single portal within the patient to perform a wide range of simultaneous  
30 procedures.

According to one embodiment of the present invention, as



-15-

depicted in FIG. 1, a device 10 is provided for use in percutaneous surgery which includes an elongated cannula 20 having a first inner diameter  $D_I$  and an outer diameter  $D_O$  sized for percutaneous introduction into a patient. The cannula 20 also includes a distal working end 21 and an opposite proximal end 22. The cannula defines a working channel 25 between the ends 21, 22 having a second diameter  $d_2$  equal to the first inner diameter  $D_I$  sized for receiving a tool therethrough. The cannula has a length along its longitudinal axis L that is sized to pass through the patient from the skin to an operative site or working space. In some cases, the working space may be adjacent a vertebra or disc, or in the spinal canal.

An elongated viewing element 50 is mountable inside cannula 20 adjacent the working channel 25. The viewing element 50 has a first end 51 connectable to a viewing apparatus, such as an eyepiece or camera, and an opposite second end 52 disposed or positionable adjacent the distal working end 21 of the cannula 20. The particular elongated viewing element 50 is not critical to the invention. Any suitable viewing element is contemplated that creates an optical or image transmission channel. In one embodiment, the elongated viewing element 50 includes a fiber optic scope 54 and a lens 55 at the second end 52. Preferably, the fiber optic scope includes illumination fibers and image transmission fibers (not shown). Alternatively, the viewing element may be a rigid endoscope or an endoscope having a steerable or bendable tip.

One advantage of this invention is that it provides optics which are movable relative to the cannula 20. Because the optics are movable, it is not necessary to provide a fluid-maintained work space. The optics can be removed, cleaned and replaced while the cannula is

-16-

percutaneously positioned within the patient over the working space. Any configuration which allows the optics to be movably supported adjacent the working channel 25 is contemplated. In one embodiment, shown in FIGS. 1-3, a fixture 30 is provided for mounting the elongated viewing element 50 to the cannula 20. Preferably, the fixture 30 includes a housing 31 attachable to the proximal end 22 of the cannula 20. The working channel opening 35 is sized to substantially correspond to the second diameter  $d_2$  of the working channel 25 to receive tools. The fixture 30 includes a housing 31 which defines a working channel opening 35 arranged to communicate with the working channel 25 when the fixture 30 is mounted to the cannula 20. The working channel opening 35 is sized to receive tools therethrough for passage through the working channel 25. In the embodiments shown in FIGS. 1-3, the fixture 30 is configured to mount the viewing element 50 within the working channel 25.

The housing 31 also defines an optics bore 60 adjacent the working channel opening 35. The optics bore 60 has a longitudinal axis  $\ell$  that is preferably substantially parallel to the axis  $L$  of the cannula and working channel. The optics bore 60 is preferably sized to removably receive the elongated viewing element 50 therethrough. The fixture 30 preferably supports the viewing element 50 for movement within the optics bore 60 along the longitudinal axis  $\ell$  of the bore 60 to extend or retract the lens 55 relative to the distal working end 21 of the cannula 20. The retractable/extendable feature of the optics of this invention provides an advantage over prior endoscopes because it eliminates the requirement for a fluid workspace. While the device 10 and its viewing element 50 can be easily used in a fluid environment, the fluid is not essential for the system to operate, contrary to prior

-17-

systems. Furthermore, many of the prior endoscopes were not suited to access certain areas because of their large diameters. For example, prior endoscopes could not access the spinal canal. However, with this invention, access to the spinal canal is not limited by the diameter of the channel or cannula. The cannula 20 can be left behind in the soft tissue or supported by the lamina while the second end 52 of the elongated viewing element 50 can be advanced into the spinal canal along with any spinal instruments which have been inserted into the working channel 25.

Preferably the fixture 30 also supports the viewing element 50 for rotation within the optics bore 60 about the longitudinal axis  $l$  of the bore 60. The lens 55 of the viewing element 50 defines an optical axis  $A_0$ . As in many endoscopes, the optical axis  $A_0$  can be offset at an angle relative to the longitudinal axis  $l$  of the optics bore 60. This feature allows the optical axis  $A_0$  of the lens to be swept through a conical field of view  $F$  for greater visibility of the working space. The fixture 30 can further be configured so that the viewing element 50 is rotatable relative to the cannula 20. In this embodiment, the housing 31 is rotatable relative to the cannula 20 so that the second longitudinal axis  $l$  of the optics bore 60 rotates about the longitudinal axis  $L$  of the working channel 25. The rotatable features of this invention allows visualization of the entire working space. This feature also aids in simplifying the surgical procedure because the optics 50 and accompanying fittings can be moved out of the way of the surgeon's hands and tools passing through the working channel.

In one embodiment depicted in FIG. 3, the housing 31 defines a receiver bore 40 having an inner diameter  $d_I$  slightly larger than the outer diameter  $D_0$  of the cannula

-18-

20. In this configuration, the proximal end 22 of the cannula 20 can be received within the receiver bore 40 so that the housing 31 can rotate about the proximal end 22 of the cannula 20. As shown in FIG. 3, the housing 31 also includes an upper bore 41 which is contiguous with the  
5 working channel opening 35 and the receiver bore 40. In one embodiment, the optics bore 60 is disposed within the upper bore 41 of the housing 31.

10 In a preferred embodiment depicted in FIG. 2, the optics bore 60 is defined by a C-shaped clip 61 disposed within the upper bore 41. Preferably, the C-shaped clip 61 is formed of a resilient material and the optics bore 60 defined by the clip 61 has an inner diameter  $D_i$  that is slightly less  
15 than the outer diameter of the elongated viewing element 50. When the viewing element 50 is pushed into the optics bore 60 it resiliently deflects the C-shaped clip 61. The resilience of the clip 61 provides a gripping force on the element 50 to hold it in the desired position, while still allowing the element 50 to be repositioned.

20 Alternatively, the optics bore 60 can have an inner diameter larger than the outer diameter of the viewing element. In this instance, the viewing element 50 can be supported outside the device 20, either manually or by a separate support fixture.

25 Preferably the device 10 provides engagement means for securely yet rotatably engaging the fixture 30 to the cannula 20. Most preferably, the fixture 30 is configured to engage a standard cannula 20. Engagement means can be disposed between the housing 31 and the cannula 20 when the  
30 fixture 30 is mounted to the proximal end 22 of the cannula 20 for providing gripping engagement between the housing 31 and the cannula 20. In one embodiment depicted in FIG. 3

-19-

the engagement means includes a number of grooves 32 within the receiver bore 40 and a resilient sealing member, such as an O-ring (see FIG. 11) disposed in each groove 32. The sealing members, or O-rings, disposed between the housing 31 and the outer diameter  $D_0$  of the cannula 20 rotatably secure the fixture 30 to the cannula 20. The O-rings provide sufficient resistance to movement to hold the fixture 30 in a selectable position on the cannula. In another embodiment, the housing 31 defines a receiver bore 40 which has an inner diameter  $d_1$  which is only slightly larger than the outer diameter  $D_0$  of the cannula 20 so that the housing 31 can rotate freely about the cannula 20.

The working channel 25 and the working channel opening 35 are both sized to receive a tool or instrument therethrough. Preferably, the working channel opening 35 of the housing 31 has a diameter  $D_w$  which is substantially equal to the inner diameter  $d_2$  of the working channel 25 so that the effective diameter of the working channel is not reduced by the fixture 30. This configuration provides a maximum amount of space for the insertion of tools into the working channel 25. The present invention is advantageous because standard micro-surgical spinal tools can be inserted into the working channel and manipulated to perform a surgical procedure. The present invention is particularly advantageous because the working channel 25 will simultaneously accept a plurality of movable instruments. No other known prior art device has a working channel that accepts more than one movable instrument at a time through a single port. Therefore, according to this invention, an entire percutaneous surgical procedure can be performed through the working channel 25 of the device 10 under direct visualization using the viewing element 50 disposed within the optics bore 60.

-20-

In accordance with the present embodiment, the components of the device 10 are cylindrical in configuration. In other words, the cannula 20, working channel 25 and fixture 30 have corresponding cylindrical configurations which yield the various diameters  $D_i$ ,  $D_o$ ,  $D_w$  and  $d_2$ . In accordance with other embodiments contemplated as part of the invention, these diameters may be non-circular inner and outer dimensions, such as oval or square shaped. For example, a cannula 20 modified to a square cross-section would still provide a large working channel, such as working channel 25. Likewise, a corresponding fixture 30 have a square cross-section would also provide a large working channel opening  $D_w$ . In the case of non-circular configurations, the fixture 30 in accordance with the present embodiment would be unable to rotate around the circumference of the cannula 20, as permitted by the circular configurations. On the other hand, even the non-circular configurations will permit axial movement of the optical viewing element and rotation of the viewing element about its own axis, as set forth more fully herein.

In accordance with a further variation of the present invention, the cannula 20 can be replaced by a similar device that is capable of maintaining a large working channel 25. For example, the cannula 20 can be replaced by an expanding cannula or dilator apparatus. In one specific embodiment, the apparatus can be a spiral wound tube that is unwound or expanded to provide the working channel dimension. Alternatively, multiple tissue dilators, such as speculae, can be expanded to create a working space. In these configurations, the fixture 30 may still be used to support the optical viewing element 50 once the expandable dilator or tissue retractor reaches its full working channel dimension.

-21-

Although standard micro-surgical instruments may be used with the present invention, this invention also contemplates certain novel tools which capitalize on and enhance the advantages of this invention.

5       According to one preferred embodiment of the invention, a tissue retractor 70 is provided as depicted in FIGS. 4-6. The retractor 70 is removably and rotatably insertable through the working channel 25 and the working channel opening 35 of the device 10. The tissue retractor 70  
10 includes a working tip 75 configured to atraumatically displace tissue as the retractor 70 is manipulated through the tissue and a body 76 having a proximal first end 77 and a distal second end 78. The second end 78 can be integral with the working tip 75 which preferably has a blunt curved  
15 end 82. In addition, the working tip 75 is also preferably bent or curved away from the body 76, as shown in FIG. 7. The body 76 is sized to be rotatably received within the cannula 20 and has a length B from the first end 77 to the second end 78 sufficient so that the first end 77 and the  
20 working tip 75 can both extend outside the cannula 20 when the body 76 is within the cannula 20.

This invention contemplates any suitable retractor for use through the working channel 25. However, retractors such as the retractor 70 depicted in FIGS. 4-6 are preferred  
25 in which the body 76 includes a curved plate 84 that is configured to conform to the inner cylindrical surface 26 of the cannula without substantially blocking the working channel 25. The curved plate 84 has a convex surface 80 and an opposite concave surface 81. In one embodiment, the  
30 curved plate 84 includes a first plate portion 85 defining a first convex surface 80 and an opposite first concave surface 81. A second plate portion 86 is integral with the

-22-

first plate portion 85 and is disposed between the first plate portion 85 and the working tip 75. The second plate portion 86 defines a second convex surface (not shown) and an opposite second concave surface 81'. Both the first plate portion 85 and the second plate portion 86 include opposite edges 90 extending substantially parallel to the length B of the body 76.

Preferably, the curved plate 84 subtends an arc  $A_1$  between the opposite edges 90 of at least 200 degrees, and most preferably 270 degrees. In a specific embodiment, the second plate portion 86 and specifically the second concave surface 81' subtends an angle that decreases along the length of the retractor. Thus, in an embodiment, the second concave surface 81' subtends an angle of about 200 degrees adjacent the first plate portion 85, decreasing to an angle of less than about 10 degrees at end 78.

An alternate embodiment of a tissue retractor according to this invention is depicted in FIGS. 8-11. This retractor 100 has a body 106 which includes a first plate portion 115 defining a first convex surface 110 and an opposite first concave surface 111 and includes first opposite edges 120 extending substantially parallel to the length B of the body 106. The first plate portion 115 subtends a first arc  $A_2$  between the first opposite edges 120. The retractor body 106 also includes a second plate portion 116 which is integral with the first plate portion 115 and is disposed between the first plate portion 115 and a working tip 105. The second plate portion 116 defines a second convex surface 110' and an opposite second concave surface 111' and includes second opposite edges 120' extending substantially parallel to the length B. The second plate portion 116 subtends a second arc  $A_3$  between the second opposite edges 120' that is different from the first arc  $A_2$  in this



-23-

embodiment. Preferably, the first arc  $A_2$  subtends an angle of less than 180 degrees and the second arc  $A_3$  subtends an angle of more than 180 degrees. Most preferably, the first arc  $A_2$  subtends an angle of about 90 degrees and the second arc  $A_3$  subtends an angle of about 270 degrees.

The retractors of this invention may be provided with means for engaging the retractors 70, 100 within the working channel 25 of the cannula 20. For example, the convex surfaces 80, 110 can be configured to have a diameter that is greater than the diameter  $D_I$  of the inner cylindrical surface 26 of the cannula 20. In that case, the body 76, 106 may be formed of a resilient material that is deformable to be insertable into the cannula 20 so that the convex surface 80, 110 is in contact with the inner cylindrical surface 26 of the cannula 20. When the body 76, 106 is deformed, it exerts an outward force against the surface 26 to frictionally hold the retractor in its selected position.

The preferred components provided by this invention are configured so that multiple tools and instruments can be accepted and manipulated within the working channel 25 of the cannula 20. The components are also configured so that more than one surgeon may manipulate instruments through the working channel 25 of the cannula 20 at one time. For example, one surgeon may be manipulating the retractor while another surgeon is drilling into a bone. The curvature of the body 76, 106 of the retractors 70, 100 provides more working space and increases visibility. Another feature is that the long axis of the component can be placed in the working channel 25 while a bend in the handle portion keeps hands away from the channel 25 so that more than one surgeon can work in the channel 25 and more tools can be placed in

-24-

the channel 25. The retractors shown in FIGS. 4-11 each comprise an arm 71, 101 attached to the proximal first end 77, 107 of the body 76, 106. Preferably, as shown in FIGS. 4-11, the arm 71, 101 is at an angle  $\alpha$  which is less than 180 degrees from the longitudinal axis of the length L of the body 76. Most preferably, the angle  $\alpha$  is about 90 degrees so that the arm 71, 101 is substantially perpendicular to the length L of the body 76, 106. Preferably, the arm 71, 101 has a gripping surface 72, 102 to facilitate manipulation of the retractor 70, 100.

The present invention also provides tissue dilators usable with the device 10. Any dilator which is insertable into the working channel 25 of the cannula 20 is contemplated; however, a preferred dilator provided by this invention is depicted in FIG. 12. A dilator 130 preferably includes a hollow sleeve 135 defining a channel 131. The channel 131 allows the dilator 130 to be placed over a guidewire (not shown) or other dilators. The hollow sleeve 135 has a working end 136 defining a first opening 132 in communication with the channel 131 and an opposite end 137 defining a second opening 133. The working end 136 is tapered to a tapered tip 138 to atraumatically displace tissue. Preferably, a gripping portion 140 is provided on the outer surface 141 of the sleeve 135 adjacent the opposite end 137. In one embodiment, the gripping portion 140 is defined by a plurality of circumferential grooves 142 defined in the outer surface 141. The grooves 142 are configured for manual gripping of the dilator 130 to manipulate the dilator 130 through tissue. Preferably, the grooves 142 are partially cylindrical. In the embodiment shown in FIG. 12, the gripping portion 140 includes a number of circumferential flats 143 each of the circumferential grooves 142. The grooves 142 have a first width  $W_1$  along

-25-

the length of the sleeve 135 and the flats 143 have a second width  $W_2$  146 along the length. Preferably, the first and second widths  $W_1$  and  $W_2$  are substantially equal.

5 The present invention has application to a wide range of surgical procedures, and particularly spinal procedures such as laminotomy, laminectomy, foramenotomy, facetectomy and discectomy. Prior surgical techniques for each of these procedures has evolved from a grossly invasive open  
10 surgeries to the minimally invasive techniques represented by the patents of Kambin and Shapiro. However, in each of these minimally invasive techniques, multiple entries into the patient is required. Moreover, most of the prior minimally invasive techniques are readily adapted only for a posterolateral approach to the spine. The devices and  
15 instruments of the present invention have application in an inventive surgical technique that permits each of these several types of surgical procedures to be performed via a single working channel. This invention can also be used from any approach and in other regions besides the spine.  
20 For instance, the invention contemplates apparatus appropriately sized for use in transnasal, transphenoidal and pituitary surgeries.

The steps of a spinal surgical procedure in accordance with one aspect of the present invention are depicted in  
25 FIG. 10. As can be readily seen from each of the depicted steps (a)-(i), the present embodiment of the invention permits a substantially mid-line or medial posterior approach to the spine. Of course, it is understood that many of the following surgical steps can be performed from  
30 other approaches to the spine, such as posterolateral and anterior. In a first step of the technique, a guidewire 150 can be advanced through the skin and tissue into the laminae M of a vertebral body V. Preferably, a small incision is

made in the skin to facilitate penetration of the guidewire through the skin. In addition, most preferably the guidewire, which may be a K-wire, is inserted under radiographic or image guided control to verify its proper positioning within the laminae L of the vertebra V. It is, of course, understood that the guidewire 150 can be positioned at virtually any location in the spine and in any portion of a vertebra V. The positioning of the guidewire is dependent upon the surgical procedure to be conducted through the working channel cannula of the present invention. Preferably, the guidewire 150 is solidly anchored into the vertebral bone, being tapped by a mallet if necessary.

In subsequent steps of the preferred method, a series of tissue dilators are advanced over the guidewire 150, as depicted in steps (b)-(d) in FIG. 10. Alternatively, the dilators can be advanced through the incision without the aid of a guidewire, followed by blunt dissection of the underlying tissues. In the specific illustrated embodiment, a series of successively larger dilators 151, 152 and 153 are concentrically disposed over each other and over the guidewire 150 and advanced into the body to sequentially dilate the perispinous soft tissues. Most preferably, the tissue dilators are of the type shown in FIG. 9 of the present application. In a specific embodiment, the dilators have successively larger diameters, ranging from 5mm, to 9mm to 12.5mm for the largest dilator. Other dilator sizes are contemplated depending upon the anatomical approach and upon the desired size of the working channel.

In the next step of the illustrated technique, the working channel cannula 20 is advanced over the largest dilator 153, as shown in step (e), and the dilators and guidewire 150 are removed, as shown in step (f).

-27-

Preferably, the working channel cannula 20 has an inner diameter  $D_I$  of 12.7mm so that it can be easily advanced over the 12.5mm outer diameter of the large dilator 153. Larger working channel cannulas are contemplated depending upon the anatomical region and surgical procedure.

With the cannula 20 in position, a working channel is formed between the skin of the patient to a working space adjacent the spine. It is understood that the length of the cannula 20 is determined by the particular surgical operation being performed and the anatomy surrounding the working space. For instance, in the lumbar spine the distance between the laminae M of a vertebra V to the skin of the patient requires a longer cannula 20 than a similar procedure performed in the cervical spine where the vertebral body is closer to the skin. In one specific embodiment in which the cannula 20 is used in a lumbar discectomy procedure, the cannula has a length of 87mm, although generally only about half of the length of the cannula will be situated within the patient during the procedure.

In accordance with the present surgical technique, the working channel cannula 20 is at least initially only supported by the soft tissue and skin of the patient. Thus, in one aspect of the preferred embodiment, the cannula 20 can include a mounting bracket 27 affixed to the outer surface of the cannula (FIG. 10(f), FIG. 11). This mounting bracket 27 can be fastened to a flexible support arm 160, which can be of known design. Preferably, the flexible support arm 160 is engaged to the bracket 27 by way of a bolt and wing nut 161, as shown in FIG. 10 (i) and in more detail in FIG. 11, although other fasteners are also contemplated. This flexible arm 160 can be mounted on the surgical table and can be readily adjusted into a fixed

-28-

position to provide firm support for the cannula 20. The flexible arm 160 is preferred so that it can be contoured as required to stay clear of the surgical site and to allow the surgeons adequate room to manipulate the variety of tools that would be used throughout the procedure.

Returning to FIG. 10, once the cannula 20 is seated within the patient, the fixture 30 can be engaged over the proximal end of the cannula 20. The fixture 30, as shown in FIGS. 2 and 3 and as described above, provides an optics bore 60 for supporting an elongated viewing element, such as element 50 shown in step h. In accordance with the invention, the viewing element 50 is advanced into the fixture 30 and supported by the optics bore 60 (FIG. 2). In one specific embodiment, the element 50 is most preferably a fiber optic scope, although a rod lens scope, "chip on a stick" or other viewing scopes may be utilized. In the final step (i) of the procedure shown in FIG. 10, the flexible arm 160 is mounted to the bracket 27 to support the cannula 20 which in turn supports the optical viewing element 50. This final position of step (i) in FIG. 10 is shown in more detail in FIG. 11. The viewing element 50 can be of a variety of types, including a rigid endoscope or a flexible and steerable scope.

With the viewing element or scope 50 supported by the fixture 30 the surgeon can directly visualize the area beneath the working channel 25 of the cannula 20. The surgeon can freely manipulate the viewing element 50 within the working channel 25 or beyond the distal end of the cannula into the working space. In the case of a steerable tip scope, the second end 52 of the viewing element 50, which carries the lens 55, can be manipulated to different positions, such as shown in FIG. 11. With virtually any type of viewing element, the manipulation and positioning of

-29-

the scope is not limited by the working channel 25, in contrast to prior systems.

Preferably, the positioning capability provided by the fixture 30 is utilized to allow extension of the lens 55 into the working space or retraction back within the cannula 20, as depicted by the arrows T in FIG. 1. Also the fixture preferably accommodates rotation of the element 50 about its own axis (arrows R in FIG. 1) to vary the viewing angle provided by the angled lens 55, or rotation of the entire viewing element 50 about the cannula 20 and around the circumference of the working channel 25, as shown by the arrows N in FIG. 1. In this manner, the surgeon is provided with a complete and unrestricted view of the entire working space beneath the working channel 25. In instances when the fixture 30 is rotated about the cannula 20, the viewing orientation of the optics (i.e., left-right and up-down) is not altered so the surgeon's view of the procedure and surrounding anatomy is not disturbed.

Another advantage provided by the single working channel cannula 20 of the present invention, is that the cannula can be readily positioned over an appropriate target tissue or bone, to thereby move the working space as necessary for the surgical procedure. In other words, since the working channel cannula 20 is freely situated within the patient's skin and tissue, it can be manipulated so that the working space beneath the cannula 20 is more appropriately centered over the target region of the spine. Repositioning of the cannula 20 can be performed under fluoroscopic guidance. Alternatively, the cannula may be fitted with position sensing devices, such as LEDs, to be guided stereotactically. As the cannula is being repositioned, the surgeon can also directly visualize the spine through the viewing element 50.

Once the position of the cannula 20 is established and a working space is oriented over the proper target tissue, a variety of tools and instruments can be extended through the working channel 25 to accomplish the particular surgical procedure to be performed. For instance, in the case of a laminotomy, laminectomy, foramenotomy or facetectomy, a variety of rongeurs, curettes, and trephines can be extended through the working channel opening 35 (see FIG. 2) and through the working channel 25 of the cannula 20 (see FIG. 11) into the working space. It is understood that these various tools and instruments are designed to fit through the working channel. For instance, in one specific embodiment, the working channel 25 through the cannula 20 can have a maximum diameter  $d_2$  of 12.7mm. However, with the viewing element 50 extending into the working channel 25, the effective diameter is about 8mm in the specific illustrated embodiment, although adequate space is provided within the working channel 25 around the viewing element 50 to allow a wide range of movement of the tool or instrument within the working channel. The present invention is not limited to particular sizes for the working channel and effective diameter, since the dimensions of the components will depend upon the anatomy of the surgical site and the type of procedure being performed.

Preferably, each of the tools and instruments used with the working channel cannula 20 are designed to minimize obstruction of the surgeon's visualization of and access to the working space at the distal end of the working channel cannula. Likewise, the instruments and tools are designed so that their actuating ends which are manipulated by the surgeon are displaced from the working channel cannula 20. One such example is the tissue retractor shown in FIGS. 4-8. With these retractors, the handles that are manually



-31-

gripped by the surgeon are offset at about a 90 degree angle relative to the longitudinal axis of the tool itself.

In accordance with one aspect of the present invention, the surgical procedures conducted through the working channel cannula 20 and within the working space at the distal end of the cannula are performed "dry" - that is, without the use of irrigation fluid. In prior surgical techniques, the working space at the surgical site is fluid filled to maintain the working space and to assist in the use of the visualization optics. However, in these prior systems the visualization optics were fixed within the endoscope. In contrast, the device 10 of the present invention allows a wide range of movement for the viewing element 50 so that the lens 55 can be retracted completely within the working channel 25 of the cannula 20 to protect it from contact with the perispinous tissue or blood that may be generated at the surgical site.

Moreover, since the viewing element 50 is removable and replaceable, the element 50 can be completely removed from the fixture 30 so that the lens 55 can be cleaned, after which the viewing element 50 can be reinserted into the fixture and advanced back to the working space. Under these circumstances, then, the need for irrigation is less critical. This feature can be of particular value when cutting operations are being performed by a power drill. It has been found in prior surgical procedures that the use of a power drill in a fluid environment can cause turbulence or cavitation of the fluid. This turbulence can completely shroud the surgeon's view of the surgical site at least while the drill is being operated. With the present invention, the dry environment allows continuous viewing of the operation of the power drill so that the surgeon can quickly and efficiently perform the necessary cutting procedures.

While the present invention permits the surgeon to conduct surgical procedures in the working space under a dry environment, irrigation may be provided separately through the working channel 25. Alternatively, the viewing device 50 itself may include a tube 54 supported by the fitting 53 through which modest amounts of fluid can be provided to keep the visualization space clear. In addition, during a discectomy, aspiration of the excised tissue is preferred, and irrigation will frequently assist in rapid removal of this tissue. Thus, separate irrigation and aspiration elements can also be inserted through the working channel 25 as required by the procedure.

As necessary, aspiration can be conducted directly through the working channel 25 of the cannula 20. In one specific embodiment, an aspiration cap 165 is provided as shown in FIGS. 11 and 12. The cap 165 includes a body 166 which defines a mating bore 167 having an inner diameter  $d_b$  larger than the outer diameter  $D_h$  of the housing 31 of fitting 30. A tool opening 168 is provided in communication with the mating bore 167. When the aspiration cap 165 is mounted over the housing 31, as shown in FIG. 11, the tool opening 168 communicates directly with the upper bore 41 and provides the same entry capabilities as the working channel opening 35 of the housing 31. The aspiration cap 165 is also provided with a tube receiver bore 169 which intersects the mating bore 167. The receiver bore 169 is configured to receive an aspiration tube through which a vacuum or suction is applied. In certain instances, the tool opening 168 may be covered while suction is applied through the tool receiver bore 169 and mating bore 167, and ultimately through the working channel 25. Covering the opening 168 can optimize the aspiration effect through the working channel.

-33-

Returning again to the surgical technique of one embodiment of the present invention, once the working channel cannula 20 and the optics 50 are in position, as depicted in FIG. 10 step (i) and FIG. 11, the paraspinous tissue can be reflected using instruments as described above, and a laminectomy performed using various rongeurs, currettes and drills. As necessary, the cannula 20 can be angled to allow a greater region of bone removal, which may be necessary for access to other portions of the spinal anatomy. In some instances, access to the spinal canal and the posterior medial aspects of the disc annulus may require cutting a portion of the vertebral bone that is greater than the inner diameter of the working channel 25. Thus, some manipulation of the cannula 20 may be necessary to permit removal of a greater portion of bone. In other operations, multi-level laminectomies or foramenotomies may be necessary. In this instance, these multi-level procedures can be conducted by sequentially inserting the working channel cannula 20 through several small cutaneous incisions along the spinal mid-line. Alternatively, several working channel cannulas 20 can be placed at each of the small cutaneous incisions to perform the multi-level bone removal procedures.

Again, in accordance with the preferred illustrated surgical technique, an opening is cut into the laminae M of the vertebra V providing direct visual access to the spinal canal itself. As necessary, tissue surrounding the spinal nerve root can be removed utilizing micro surgical knives and currettes. Once the spinal nerve root is exposed, a retractor, such as the retractors shown in FIGS. 4-8, can be used to gently move and hold the nerve root outside the working space. In one important aspect of the two retractors 70, 100, the portion of the retractor passing

-34-

through the working channel 25 generally conforms to the inner surface of the cannula 20 so that the working channel 25 is not disrupted by the retractor tool. Specifically, the effective diameter within the working channel 25 is reduced only by the thickness of the curved plates 84, 114 of the retractors 70, 100. In one specific embodiment, this thickness is about 0.3mm, so it can be seen that the tissue retractors do not significantly reduce the space available in the working channel 25 for insertion of other tools and instruments.

With the tissue retractor in place within the working channel 25, bone within the spinal canal, such as may occur in a burst fracture, can be removed with a curette or a high speed drill. Alternatively, the fractured bone may be impacted back into the vertebral body with a bone impactor. At this point, if the spinal procedure to be performed is the removal of epidural spinal tumors, the tumors can be resected utilizing various micro-surgical instruments. In other procedures, the dura may be opened and the intradural pathology may be approached with micro-surgical instruments passing through the working channel cannula 20. In accordance with the specific illustrated technique, with the nerve root retracted posterior medial disc herniations can be readily excised directly at the site of the herniation.

In another embodiment of the invention, a working channel cannula, such as cannula 20, is provided with a fixture 170 for supporting optics and irrigation/aspiration components. In accordance with this embodiment, the fixture 170 includes a scope body 171 which is shown most clearly in FIGS. 13, 14, 16 and 17. The scope body 171 includes a clamping ring 172 configured to encircle the outer surface 23 of the cannula 20. In particular, the clamping ring 172 includes an inner clamping surface 175 (see FIG. 14). That

-35-

clamping surface 175 has substantially the same configuration and dimension as the outer surface 23 of the cannula 20. The clamping ring 172 includes clamp arms 173a, b at the free ends of the ring. The clamp arms 173a, b  
5 define a slot 174 (see FIG. 17) therebetween.

The clamping ring 172 is integral with a support column 176 forming part of the scope body 171. A column slot 177 is formed in the support column 176, with the column slot 177 being contiguous with the slot 174 between the clamp  
10 arms 173a, b. As described in more detail herein, the slots 174 and 177 permit the clamp arms 173a, b to be compressed toward each other to thereby compress the clamping surface 175 of the ring 172 about the outer surface 23 of the  
cannula 20. In this manner, the fixture 170 can be affixed  
15 at a specific position on the cannula 20. It is understood that when the clamping ring 172 is loosened, the fixture 170 is free to rotate about the circumference of the cannula 20 in the direction of the arrow N. In addition, the fixture 170 can translate along the longitudinal length of the  
20 cannula 20 in the direction of the arrow T. Of course, the direction of the travel distance of the fixture 170 along the length of the cannula 20 is limited by the proximal end 22 and the bracket 27 used to engage a supporting flexible arm 160 as described above.

25 Returning to FIGS. 13-17, additional details of the fixture 170 can be discerned. In particular, the fixture 170 includes an optics mounting body 178 that is supported by and preferably integral with the support column 176. The optics mounting body 178 defines a stop edge 179 at the  
30 interface between the support column 176 and the mounting body 178. This stop edge defines the height of the support column from the clamping ring 172 to the stop edge 179. The stop edge 179 of the optics mounting body 178 can be used to

-36-

limit the downward travel of the fixture 171 in the direction of the arrow T, which can be particularly important in embodiments of the cannula 20 that do not include the bracket 27.

5 In accordance with the present embodiment, the optics mounting body 178 defines an optics bore 180 which is configured to receive and support an optics cannula 190. The optics bore 180 can communicate with an illumination port 181 which can receive an illumination source, such as a  
10 fiber optic light cable. The optics bore 180 also communicates with an optics coupling bore 182 projecting from a front face of the fixture 170. In accordance with one specific embodiment, the fixture 170 also includes a coupling body 183 that is preferably press-fit within the  
15 optics coupling bore 182. As shown in FIG. 15, the coupling body 183 can be engaged by a coupler 184 to support a camera 185 thereon.

In a further aspect of the optics mounting body 178, an aspiration port 186 and an irrigation port 187 can be  
20 provided that communicates with the optics bore 180. Preferably, the optics cannula 190 includes channels along its length to correspond to the various ports in the optics mounting body 178. In one specific embodiment, the port 181 is not used, with the port 186 being used to receive an  
25 illumination element. As shown more particularly in FIG. 23, the port 187 can be connected to an aspiration circuit. In particular, the port 187 can be engaged to an aspiration tube 225 which carries a flow control valve 226 and Luer®  
fitting 227 at its free end. The Luer® fitting 227 can  
30 engage a source of irrigation fluid or aspiration vacuum pressure depending upon the particular use envisioned for the port 187 and a corresponding channel within the optics cannula 190.

-37-

In accordance with a method of the present invention, the port 187 is used as an aspiration port with the Luer® fitting 227 connected to a vacuum source. It is understood that the port 187 is in fluid communication with a  
5 corresponding channel in the optics cannula 190 so that suction applied through the tube 225 and port 187 is drawn through the distal or working end 192 of the optics cannula 190. The working end 192 is at the surgical site so that the suction draws air through the working channel 25 of the  
10 cannula 20, to the surgical site and through the aspiration/irrigation channel in the optics cannula 190. It has been found that providing aspiration suction in this manner eliminates smoke that may be developed during operation of certain instruments, such as a Bovie.  
15 Moreover, the suction applied through the port 187 can draw air across the lens 191 (see FIG. 14, 15) of the optics cannula 190, to prevent fogging of the lens. If a separate aspiration tube is extended through the working channel, defogging of the lens 191 is best achieved with the opening  
20 of the aspiration tube adjacent the lens. In this manner, the provision of aspiration vacuum through the working channel and working space virtually eliminates the need to retract the optics cannula 190 to clean the lens 191. This is in contrast to prior devices in which either the lens had  
25 to be removed from the surgical site for cleaning or devices in which substantial flow of fluid is required to keep the lens clean and clear.

Looking now to FIGS. 18-22, details of a barrel clamp mechanism 195 are shown. The barrel clamp mechanism 195  
30 compresses the arms 173a, b of the clamping ring 172 together to clamp the fixture 170 to the cannula 20. The barrel clamp mechanism 195 includes a barrel cam 196 disposed immediately adjacent one of the clamp arms 173b,

-38-

and a lever arm 197 that operates to compress the barrel cam 196 against the clamp arm 173. A shoulder screw 198 fixes each of these components together. Specifically, the shoulder screw 198 includes a threaded shank 199 that is configured to engage a mating threaded bore 202 in one of the clamp arms 173a. The shoulder screw 198 includes a bearing shank 200 that is smooth or non-threaded. The bearing shank 200 is received within a bearing bore 203 in the clamp arm 173b, a colinear bearing bore 204 in the barrel cam 196, and a bearing bore 205 in the lever arm 197. The shoulder screw 198 further includes an enlarged head 201 which is preferably received within a head recess 206 in the lever arm 197 (see FIG. 19). Preferably, the enlarged head 201 of the shoulder screw includes a driving tool recess to mate with a driving tool to thread the threaded shank 199 of the screw into the mating threaded bore 202 of the clamp arm 173a. It is understood that the barrel cam 196 and lever arm 197 are free to rotate about the bearing shank 200 of the shoulder screw 198.

Referring specifically to FIGS. 18-19, the lever arm 197 includes an arm 210 that is integral with a body 211. The bearing bore 205 and head recess 206 are defined in the body 211. The body 211 defines a pair of projections 312 on opposite sides of the bearing bore 205. As depicted in FIG. 19, each of the projections 212 includes a rounded tip 213 to provide a smooth sliding surface.

Referring specifically to FIGS. 20-21, the barrel cam 196 includes a flat face 215 that faces the clamp arm 173b. Preferably, the flat face provides for smooth rotation of the barrel cam 196 relative to the stationary arm 173b. The opposite face of the barrel cam 196 is a cam face 216 that includes a pair of diametrically opposite cam portions 217. In accordance with the preferred embodiment, the cam



-39-

portions 217 define a ramp 218 that is inclined upward to a detent recess 219. Each detent recess 219 terminates in a stop 220 that is higher relative to the base detent recess 219 than the ramp 218.

5        In the assembled configuration, the barrel clamp mechanism 195 operates to compress the arms 173a, b of the clamping ring 172 together when the lever arm 197 is rotated about the shoulder screw 198. Specifically, as the lever arm 197 is rotated, the projections 212 slide on their  
10        rounded tip 213 along the ramps 218 until the rounded tips 213 fall within the opposite detents 219. As the projections 212 move up the ramps 218, the projections 212 push the barrel cam 196 toward the clamp arms 173a, b. More specifically, since the opposite clamp arm 173a is held  
15        relatively fixed by the threaded shank 199 of the shoulder screw 198, the movement of the barrel cam 196 presses the clamp arm 173b against the relatively stationary clamp arm 173a. As this occurs, the clamping ring 172 is tightened around the outer surface 23 of the cannula 20. When the  
20        projections 212 are seated within the recesses 219 of the barrel cam 196, the fixture is locked onto the cannula 20. It is understood that the recesses 219 are shallow enough to permit ready manual disengagement of the projections 212 from the recesses 219 as the lever arm 197 is rotated in the  
25        opposite direction.

      In one specific embodiment, the detent recesses 219 are 180° opposite each other. The ramps 218 are curved and subtend an angle of about 90°. Thus, the lever arm 197 rotates through 90° to move the projections 212 from one end  
30        of the cam ramps 218 to the recesses 219. In the preferred embodiment, the lever arm ninety degree movement (arrow J in FIG. 15) moves the arm from a first position in which the arm 197 is substantially parallel to the cannula, to a

-40-

second position in which the arm is substantially perpendicular to the cannula. Most preferably, in the second position the arm is oriented immediately adjacent the cannula, rather than projecting away. In the first and second positions, the lever arm 197 maintains a low profile so as not to interfere with the surgeon's manipulation of tools and instruments through the working channel. In a specific embodiment, the first position of the lever arm corresponds to the loose or unlocked position of the barrel clamp mechanism 195, while the second position corresponds to the locked configuration.

In order for the barrel clamp mechanism 195 to function properly, it is preferred that the barrel cam 196 remain stationary relative to the moveable lever arm 197, with the exception that the barrel cam 196 is free to translate along the length of the shoulder screw 198. Consequently, the clamp arm 173b includes a recess 222 that has a configuration substantially similar to the outer periphery of the barrel cam 196. In this manner, the barrel cam can be slightly indented within the clamp arm 173b so that the cam is unable to rotate about the shoulder screw 198 as the lever arm 197 is pivoted.

In accordance with one specific embodiment of the invention, the components of the fixture 170 are formed of a flexible and resilient material. For example, the scope body 171 can be formed of a plastic, such as polycarbonate. The scope body 171 lends itself particularly well to typical plastic molding techniques. Likewise, the barrel cam 196 and lever arm 197 can be molded from a plastic material. In one specific embodiment, these components are formed of Delrin®, since Delrin® provides a smooth surface for the relative movement between the projections 212 on the lever arm 197 and the cam face 216 of the barrel cam 196.

-41-

It is understood that the travel of the barrel clamp mechanism 195 can be calibrated sufficient to tightly compress the clamping rings 172 about the cannula 20. It is also understood that this compression must not be so great as to compromise the integrity or strength of the cannula 20. In one specific embodiment, the slot 174 is larger than the maximum travel of the barrel clamp mechanism 195 so that the projections 212 of the lever arm 197 can rest solidly within the detent recesses 219 of the barrel cam 196. In accordance with one specific embodiment, the slot 174 has a dimension of 2.0mm while the throw of the barrel clamp mechanism 195 achieved by the barrel cam 196 is 1.0mm.

In accordance with the present embodiment of the invention, the fixture 170 supports an optics cannula 190 in a fixed orientation relative to the scope body 171. In other words, in this specific embodiment, the optics cannula 190 is not permitted to rotate about its axis as could the scope 50 of the embodiment shown in FIG. 1. The lens 191 is therefore mounted at an angle B relative to the distal end of the optics cannula 190. In one specific embodiment, the lens 191 is situated at an angle B of 30°. In addition, in the specific embodiment, the lens has an optical axis that is angled toward the center of the working space 25 or the cannula 20. While the lens 191 has a fixed orientation relative to the scope body 171, the lens can still be rotated around the working space by rotation of the fixture 170 about the outer surface 23 of the cannula 20. In addition, the lens 191 and the optical system provide a depth of field of view that allows the surgeon to view anatomy outside the working channel 25.

Even in the present specific embodiments, the fixture 170 allows rotation of the optics cannula 190 around the

-42-

working space and translation of the optics cannula 190 and 191 along the longitudinal axis of the working channel 25. Of course, it is understood that the surgeon can achieve these motions by releasing the barrel clamp mechanism 195 and then re-engaging the clamp by rotating the lever arm 197 to its locked position. Preferably, the optics cannula 190 is sized so that the lens 191 can project beyond the distal end 21 of the cannula 20. Similarly, in the preferred embodiment, the fixture 170 allows the retraction of the lens 191 and optics cannula 190 within the working channel 25 and cannula 20.

In one specific embodiment, the fixture 170 permits up to 15mm travel along the direction of the arrow T with 7.5mm of the travel being within the working space 25 and 7.5mm of the travel being beyond the distal end 21 of the cannula 20. In accordance with the specific embodiment, this 15mm travel distance is related to the height of the support column 176 from the top of the clamping ring 172 to the stop edge 179 of the optics mounting body 178. The amount of extension of the lens 191 of the optics cannula 190 beyond the distal end 21 of the cannula 20 is also based upon the overall length of the optics cannula 190 relative to the overall length of the working channel cannula 20. In one specific embodiment, the optics cannula 190 has a length of 100mm measured from the lens 191 to the stop edge 179 of the optics mounting bore 178. Of course, it is understood that the optics cannula is longer than this 100mm distance because a portion of the cannula is supported within the optics bore 180 of the optics mounting body 178. Again in the specific embodiment, the cannula 20 has an overall length of 92mm from its distal end 21 to its proximal end 22 (see FIG. 15).

-43-

In a further aspect of the invention, the overall length of the cannula, and consequently the optics cannula 190, is determined, in part, by the spinal anatomy. In particular, for applications of the present invention in the field of spinal surgery, it has been found that placement of the proximal end 22 of the working channel 25 too distant from the surgical site at the distal end 21, causes the surgeon to lose tactile feel while manipulating certain instruments. In other words, when the surgeon passes instruments through the working channel and manipulates them at the surgical site, a certain amount of "feel" is required so that the surgeon can accurately perform the respective operations with the instrument. If the distance between the surgical site and the manual end of the instrument is too great, the surgeon will not be able to stably and comfortably operate the instrument.

In accordance one beneficial aspect of the present invention, it has been found that the working channel cannula 20 must have a length that is limited relative to the distance L (FIG. 24) between the vertebral laminae and the surface of the skin. In the lumbar region of the spine, this distance is approximately 65-75mm. Consequently, in one embodiment of the invention, the working channel cannula 20 has first portion of its length somewhat less than the anatomic distance. In one specific embodiment, this length of the first portion is about 66mm from the distal end 21 to the mounting bracket 27. In some surgical applications, the mounting bracket 27 may actually rest against the skin of the patient so that the distal end 21 of the working channel cannula can be closer to the surgical site.

Further in accordance with the present invention, the remaining second portion of the length of the cannula 20

-44-

above the mounting bracket 27 is minimized. In accordance with the invention, this distance must be sufficient to permit extension and retraction of the lens 191 relative to the distal end 21 of the cannula 20. As described above, the travel of the optical lens 191 is preferably 15mm, so that the remaining length of the cannula 20 is about 26mm to accommodate this travel and to provide adequate surface for engagement by the clamping ring 172. Thus, in the preferred embodiment, the working channel cannula 20 has an overall length of 92mm. In accordance with one aspect of the invention, it has been found that the relative length between the first portion of the cannula disposed within the patient to the second portion of the cannula length situated outside the patient have a ratio of 2:1 to 3:1. In other words, the length of the first portion is between two to three times longer than the length of the second portion.

It has also been found that it is desirable to minimize the height of the fixture 170 beyond the end of the working channel cannula 20. In accordance with the present invention, the optics mounting body 178 has a height of about 21mm between the stop edge 179 and the top face of the body 178. This distance is not so great that the surgeon is restrained from manipulating instruments directly above the fixture 170. Of course, it is preferable that the surgeon manipulate the instruments directly above the proximal end 22 of the working channel 20 immediately adjacent to the fixture 170.

In the present preferred embodiment, the working channel cannula has an inner diameter of about 15mm and an outer diameter of about 16mm. Alternatively, the cannula can be provided in a smaller size for other regions of the spine. In a further specific embodiment, the cannula inner diameter is 12.7mm with a 14mm outer diameter. In another aspect of

-45-

the invention, the overall length and diameter of the working channel cannula 20 is calibrated again relative to the distance L of the spinal anatomy. With the larger diameter working channel, the surgeon can orient certain instruments at an angle relative to the longitudinal axis of the cannula 20. In specific embodiments, this angle is approximately 5-6°. It has been found that this angle, together with the large working channel 25, gives the surgeon greater flexibility and mobility within the surgical site to perform various operations. To that end, the length and diameter of the working channel cannula 20 is appropriately sized to maintain this flexibility, without getting too large. A working channel cannula 20 that has too large a diameter is less adaptable to the spinal anatomy.

In accordance with preferred methods using the device 10 of the present invention, the working space is generally limited to the region directly adjacent the laminae of a vertebra. A cannula having a diameter that is too large will interfere with the spinous process when the working space is created, and will require resection of greater amounts of tissue than is preferred for an optimal percutaneous procedure. Therefore, in accordance with one aspect of the invention, the working channel cannula has a relationship between its length and its diameter to permit tool angles through the cannula of between 5-8°. In accordance with one specific aspect of the present invention, the cannula can have a length to diameter ratio of between about 5.5:1 to 7:1. Further in accordance with the present invention, the working channel cannula has a length that is no more than 20-30mm greater than the distance L (FIG. 24) between the laminae and the skin of the patient.

One important feature of the present invention is

-46-

achieved by the large diameter of the working channel 25 in the cannula 20. This large diameter allows the surgeon or surgeons conducting the surgical procedure to introduce a plurality of instruments or tools into the working space.

5 For example, as described above, a tissue retractor and discectomy instruments can be simultaneously extended through the working channel. In that illustrated embodiment, the discectomy instruments could include a trephine for boring a hole through the disc annulus and a

10 powered tissue cutter for excising the herniated disc nucleus. Likewise, the present invention contemplates the simultaneous introduction of other types of instruments or tools as may be dictated by the particular surgical procedure to be performed. For example, an appropriately

15 sized curette and a rongeur may be simultaneously extended through the working channel into the working space. Since all operations being conducted in the working space are under direct visualization through the viewing element 50, the surgeon can readily manipulate each of the instruments

20 to perform tissue removal and bone cutting operations, without having to remove one tool and insert the other. In addition, since the surgical procedures can be conducted without the necessity of irrigation fluid, the surgeon has a clear view through the working space of the target tissue.

25 Furthermore, aspects of the invention which permit a wide range of motion to the viewing element 50 allow the surgeon to clearly visualize the target tissue and clearly observe the surgical procedures being conducted in the working space.

The surgeon can capitalize on the same advantages in

30 conducting a wide range of procedures at a wide range of locations in the human body. For example, facetectomies could be conducted through the working channel by simply orienting the working channel cannula 20 over the particular facet joints. The insertion of vertebral fixation elements



-47-

can also be accomplished through the device 10. In this type of procedure, an incision can be made in the skin posterior to the location of the vertebra at which the fixation element is to be implanted. Implementing the steps  
5 shown in FIG. 10, the cannula 20 can be positioned through the incision and tissue directly above the particular location on the vertebra to be instrumented. With the optics extending through the working channel, an insertion tool holding the vertebral fixation element can be projected  
10 through the cannula 20 and manipulated at the vertebra. In one specific embodiment, the fixation element can be a bone screw. The working channel 25 has a diameter that is large enough to accept most bone screws and their associated insertion tools. In many instances, the location of the  
15 bone screw within the vertebra is critical, so identification of the position of the cannula 20 over the bony site is necessary. As mentioned above, this position can be verified fluoroscopically or using stereotactic technology.

20 In many prior procedures, cannulated bone screws are driven into the vertebra along K-wires. The present invention eliminates the need for the K-wire and for a cannulated screw. The working channel itself can effectively operate as a positioning guide, once the cannula  
25 20 is properly oriented with respect to the vertebra. Moreover, the device 10 allows insertion of the bone screw into the vertebra to be conducted under direct vision. The surgeon can then readily verify that the screw is passing into the vertebra properly. This can be particularly  
30 important for bone screws being threaded into the pedicle of a vertebra. The working channel cannula 20 can be used to directly insert a self-tapping bone screw into the pedicle, or can accept a variety of tools to prepare a threaded bore within the pedicle to receive a bone screw.

The device 10 can also be used to prepare a site for fusion of two adjacent vertebrae, and for implantation of a fusion device or material. For example, in one surgical technique, an incision can be made in the skin posterior to a particular disc space to be fused. The incision can be made anteriorly, posteriorly or posterior laterally. If the incision is made anteriorly for anterior insertion of the working channel, it is anticipated that care will be taken to retract tissues, muscle and organs that may follow the path of the incision to the disc space. However, the device 10 of the present invention allows this tissue retraction to occur under direct vision so that the surgeon can easily and accurately guide the cannula 20 to the disc space without fear of injury to the surrounding tissue. As the tissue beneath the skin is successively excised or retracted, the working channel cannula 20 can be progressively advanced toward the anticipated working space adjacent the vertebral disc. Again under direct vision, the disc space can be prepared for implantation of fusion materials or a fusion device. Typically, this preparation includes preparing an opening in the disc annulus, and excising all or part of the disc nucleus through this opening.

In subsequent steps, a bore is cut through the disc annulus and into the endplates of the adjacent vertebrae. A fusion device, such as a bone dowel, a push-in implant or a threaded implant can then be advanced through the working channel of device 10 and into the prepared bore at the subject disc space. In some instances, the preparatory steps involve preparing the vertebral endplates by reducing the endplates to bleeding bone. In this instance, some aspiration and irrigation may be beneficial. All of these procedures can be conducted by tools and instruments

-49-

extending through the working channel cannula 20 and under direct vision from the viewing element 50.

5 In some instances, graft material is simply placed within the prepared bore. This graft material can also be passed through the working channel cannula 20 into the disc space location. In other procedures, graft material or bone chips are positioned across posterior aspects of the spine. Again, this procedure can be conducted through the working channel cannula particularly given the capability of the  
10 cannula to be moved to different angles from a single incision site in the skin.

The present invention provides instruments and techniques for conducting a variety of surgical procedures. In the illustrated embodiments, these procedures are  
15 conducted on the spine. However, the same devices and techniques can be used at other places in the body. For example, an appropriately sized working channel device 10 can be used to remove lesions in the brain. The present invention has particular value for percutaneous procedures  
20 where minimal invasion into the patient is desirable and where accurate manipulation of tools and instruments at the surgical site is required. While the preferred embodiments illustrated above concern spinal procedures, the present invention and techniques can be used throughout the body,  
25 such as in the cranial cavity, the pituitary regions, the gastro-intestinal tract, etc. The ability to reposition the viewing optics as required to visualize the surgical site allows for much greater accuracy and control of the surgical procedure. The present invention allows the use of but a  
30 single entry into the patient which greatly reduces the risk associated with open surgery or multiple invasions through the patient's skin.

-50-

In accordance with yet another aspect of the present invention, a tissue retractor apparatus 230 is provided that combines a tissue retractor 231 with an optical viewing device 232. Referring to FIGS. 25-26, the retractor apparatus 230 includes a retractor plate 234 that is affixed to a grip 235 for manual support of manipulation of the retractor. The grip 235 is at the proximal end 236 of the plate. The distal end 237 of the retractor plate preferably has a blunt tip 238 to avoid trauma to tissue upon insertion and manipulation of the tissue retractor. Preferably, the blunt tip 238 is angled slightly away from the plate 234. The retractor plate 234 defines an outer retraction surface 239 that can be configured according to the type of surgery being performed. In a preferred embodiment, the plate 234 is semi-cylindrical in configuration to permit atraumatic retraction of tissue adjacent a surgical site. In addition, the retractor plate 234 defines a channel 240 that helps define a working channel. As thus far described, the retractor 231 is substantially similar to the retractor 70 depicted in FIGS. 4-6 and as described above.

In accordance with this embodiment of the invention, an optical viewing device 232 is supported within the retractor 231 by way of a number of C-clips 245. Preferably, the C-clips 245 are formed of a resilient material, such as plastic or thin flexible metal, and are affixed to the channel 240 of the retractor plate 234. In accordance with one specific embodiment, two such C-clips 245 are provided to stably mount the optical viewing device 232 relative to the retractor 231. Preferably, the clips 245 are sized to support an optical viewing device 232 that is configured substantially identical to the viewing device 50 described above. In the preferred embodiment, the viewing device 232 has a distal tip 52 with an angled lens 54. In accordance

-51-

with this embodiment, the C-clips 245 provide a resilient friction fit to the optical viewing device 232 while still permitting relative sliding and rotation of the viewing device 232 relative to the retractor 231.

5        In accordance with the present invention, the tissue retractor apparatus 230 can be used in a variety of applications, including non-spinal applications. For example, this tissue retractor can have application in transnasal and transphenoidal surgeries, and in pituitary  
10        procedures. In surgeries of this type, it is not necessarily desirable to provide a closed cannula, such as the working channel cannula 20. Moreover, the smaller working space does not lend itself to the use of a closed cannula which would tend to restrict the space available for  
15        manipulation of surgical instruments. Consequently, a tissue retractor or speculum of the type shown in FIGS. 25-26 may be very adequate for surgeries of this type. In this instance, then the working channel is defined in part by the patient's body itself, and in part by the tissue  
20        retractor. The optical viewing device 232 is supported relative to the retractor to permit the same degrees of motion as are available with the device 10 described above.

25        While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

-52-

## WHAT IS CLAIMED:

1. A device for use in percutaneous spinal surgery, comprising:

5 an elongated cannula having a first inner dimension and an outer dimension sized for percutaneous introduction into a patient, said cannula further including a distal working end and an opposite proximal end, said cannula defining a working channel between said ends having a second dimension substantially equal to said first inner dimension and sized  
10 for receiving a tool therethrough; and

a viewing element mounted inside said cannula adjacent said working channel, said viewing element having a first end connectable to a viewing apparatus and an opposite  
15 second end disposed adjacent said distal working end of said cannula.

2. The device of claim 1 wherein said second inner dimension is sized to simultaneously receive a plurality of tools therethrough.

3. The device of claim 1, wherein said viewing element  
20 includes a lens at said second end and an image transmission channel extending therefrom.

4. The device of claim 3, wherein said viewing element is a fiber-optic cable having illumination fibers and image transmission fibers.

25 5. The device of claim 1, further comprising a fixture for mounting said viewing element to said cannula.

6. The device of claim 5, wherein said fixture is configured to mount said viewing element within said working channel.

-53-

7. The device of claim 5, wherein said fixture includes:

5 a housing attached to the proximal end of the cannula, said housing defining a working channel opening therethrough in communication with the working channel, said working channel opening sized to substantially correspond to said second dimension of said working channel to receive a tool therethrough;

10 said housing further defining an optics bore adjacent said working channel opening, said optics bore sized to receive said viewing element therethrough.

8. A device for use in percutaneous spinal surgery, comprising:

15 an elongated cannula sized for percutaneous introduction into a patient having a distal working end and an opposite proximal end and defining a working channel between said ends, said working channel having an inner dimension sized to receive a tool therethrough;

20 a viewing device having a first end connectable to a viewing apparatus and a second end including a lens positionable adjacent said working end of said cannula; and

25 a fixture supported adjacent said proximal end of said cannula adjacent to said working channel and defining an optics bore having a longitudinal axis, said optics bore sized to removably receive said viewing device therethrough, and said fixture supporting said viewing device for movement within said optics bore along the longitudinal axis of said bore to extend or retract said lens relative to said distal working end of said cannula.

30 9. The device of claim 8 wherein said viewing element includes a lens at said second end and an image transmission channel extending therefrom.

-54-

10. The device of claim 9, wherein said lens defines an optical axis, said optical axis being offset at an angle relative to said longitudinal axis of said optics bore.

11. The device of claim 9, wherein viewing element is a  
5 fiber-optic cable having illumination fibers and image transmission fibers.

12. The device of claim 8, wherein said fixture is configured to support said viewing element within said working channel.

10 13. The device of claim 8, wherein said fixture includes:

15 a housing attached to the proximal end of the cannula, said housing defining a working channel opening therethrough in communication with the working channel, said working channel opening sized to substantially correspond to said second dimension of said working channel to receive a tool therethrough;

said housing further defining said optics bore adjacent said working channel opening.

20 14. A device for use in percutaneous spinal surgery, comprising:

25 an elongated cannula having a distal working end and an opposite proximal end and defining a working channel between said ends, said working channel having an inner dimension sized to receive a tool therethrough;

a viewing device having a first end connectable to a viewing apparatus and a second end including a lens positionable adjacent said working end of said cannula; and

30 a fixture supported adjacent said proximal end of said cannula adjacent to said working channel and defining an



-55-

optics bore having a longitudinal axis, said optics bore sized to removably receive said viewing device therethrough, and said fixture supporting said viewing device for rotation within said optics bore about the longitudinal axis of said  
5 bore.

15. The device of claim 14 wherein said viewing element includes a lens at said second end and an image transmission channel extending therefrom.

16. The device of claim 15, wherein said lens defines  
10 an optical axis, said optical axis being offset at an angle relative to said longitudinal axis of said optics bore.

17. The device of claim 15, wherein said viewing element is a fiber-optic cable having illumination fibers and image transmission fibers.

18. The device of claim 14, wherein said fixture is  
15 configured to support said viewing element within said working channel.

19. The device of claim 14, wherein said fixture includes:  
20 a housing attached to the proximal end of the cannula, said housing defining a working channel opening therethrough in communication with the working channel, said working channel opening sized to substantially correspond to said second dimension of said working channel to receive a tool  
25 therethrough;

said housing further defining said optics bore adjacent said working channel opening.

20. The device of claim 14, wherein said fixture further supports said viewing device for movement within  
30 said optics bore along said longitudinal axis of said bore.

-56-

21. A device for use in percutaneous spinal surgery comprising:

an elongated cannula having a distal working end and an opposite proximal end and defining a working channel between  
5 said ends, said working channel having a first longitudinal axis and an inner dimension sized to receive a tool therethrough; and

a fixture mounted to said proximal end of said cannula, said fixture including a housing defining a working channel  
10 opening in communication with said working channel of said cannula and an optics bore for receiving a viewing device therethrough in communication with said working channel, said optics bore having a second longitudinal axis  
substantially parallel to said first longitudinal axis, said  
15 housing being rotatable relative to said cannula so that said second longitudinal axis of said optics bore rotates about said first longitudinal axis of said working channel.

22. The device of claim 21, further comprising a viewing device disposed within said optics bore, said  
20 viewing device having a first end connectable to a viewing apparatus and a second end including a lens positionable adjacent said working end of said elongated cannula.

23. The device of claim 21, wherein:  
said cannula has an outer dimension; and  
25 said housing defines a receiving bore having an inner dimension slightly larger than said outer dimension of said cannula, wherein said proximal end of said cannula is received within said receiver bore so that said housing can rotate about said proximal end of said cannula.

30 24. The device of claim 23, wherein said housing further includes an upper bore contiguous with said working

-57-

channel opening and in communication with said receiver bore, said optics bore being disposed within said upper bore of said housing.

25. The device of claim 21, wherein said optics bore is  
5 defined by a C-shaped clip.

26. The device of claim 25, wherein said C-shaped clip is formed of a resilient material and said optics bore defined by said clip has an inner dimension that is slightly less than an outer dimension of said viewing device so that  
10 said viewing device resiliently deflects said C-shaped clip when said viewing device is disposed within said optics bore.

27. The device of claim 23, wherein said housing further defines a number of grooves in said receiver bore.

28. The device of claim 27, further comprising sealing  
15 members disposed in each of said number of grooves, said sealing members disposed between said housing and said outer dimension of said cannula.

29. The device of claim 21 wherein said working channel opening has a dimension substantially equal to said inner  
20 dimension of said working channel.

30. The device of claim 21 wherein said fixture includes engagement means, disposed between said housing and said cannula when said fixture is mounted to said proximal end of said cannula, for providing a gripping engagement  
25 between said housing and said cannula.

31. The device of claim 30, wherein said engagement means includes a number of resilient rings disposed between said housing and said cannula.

-58-

32. A device for supporting a viewing device within a cannula defining a working channel, comprising:

5 a fixture mountable to said proximal end of the cannula, said fixture including a housing defining a working channel opening arranged to communicate with the working channel when said fixture is mounted to the cannula, said working channel opening sized to receive tools therethrough, and said housing further defining an optics bore for receiving a viewing device therethrough and arranged so that the viewing device received within said optics bore will extend into the  
10 working channel of the cannula when said fixture is mounted to the cannula.

33. The device of claim 32, in which the cannula defines a first longitudinal axis, wherein said optics bore defines a second longitudinal axis substantially parallel to  
15 the first longitudinal axis when said fixture is mounted on the cannula, said housing being rotatable relative to said cannula so that said second longitudinal axis of said optics bore rotates about the first longitudinal axis of the  
20 cannula.

34. The device of claim 32 in which the cannula has an outer dimension, wherein said housing defines a receiving bore having an inner dimension slightly larger than the outer dimension of the cannula, so that said housing can  
25 rotate about the cannula.

35. The device of claim 34, wherein said housing further includes an upper bore contiguous with said working channel opening and in communication with said receiving bore, said optics bore being disposed within said upper bore  
30 of said housing.

-59-

36. The device of claim 35, wherein said optics bore is defined by a C-shaped clip.

37. The device of claim 36, wherein said C-shaped clip is formed of a resilient material and said optics bore  
5 defined by said clip has an inner dimension that is slightly less than an outer dimension of the viewing device so that the viewing device resiliently deflects said C-shaped clip when the viewing device is disposed within said optics bore.

38. The device of claim 34, wherein said housing  
10 further defines a number of grooves in said receiver bore.

39. The device of claim 38, further comprising O-rings disposed in each of said number of grooves, said O-rings disposed between said housing and the outer dimension of the cannula when the cannula is disposed within said receiver  
15 bore.

40. A tissue retractor for use in percutaneous surgery through a cannula having an inner cylindrical surface, said retractor comprising:

a working tip configured to atraumatically displace  
20 tissue as the retractor is manipulated through the tissue;  
and

a body having a proximal first end and a distal second end, said second end being integral with said working tip, said body having a convex surface configured to conform to  
25 the inner cylindrical surface of the cannula when said tissue retractor is disposed within the cannula, said body sized to be rotatable received within the cannula and having a length from a said first end to a said second end sufficient so that said first end and said working tip can  
30 be outside the cannula when said body is within the cannula.

-60-

41. The tissue retractor of claim 40, wherein said working tip has a blunt curved end.

42. The tissue retractor of claim 40, wherein said body includes a curved plate defining said convex surface and an  
5 opposite concave surface.

43. The tissue retractor of claim 42, wherein said curved plate includes opposite edges extending substantially parallel to said length of said body, said curved plate subtending an arc between said opposite edges of at least  
10 200 degrees.

44. The tissue retractor of claim 43, wherein said curved plate subtends an arc between said opposite edges of about 270 degrees.

45. The tissue retractor of claim 40, wherein said body  
15 includes:

a first plate portion defining a first convex surface and an opposite first concave surface and including first opposite edges extending substantially parallel to said length of said body, said first plate portion subtending a  
20 first arc between said first opposite edges; and

a second plate portion integral with said first plate portion and disposed between said first plate portion and said working tip, said second plate portion defining a second convex surface and an opposite second concave surface  
25 and including second opposite edges extending substantially parallel to said length, said second plate portion subtending a second arc between said second opposite edges that is different from said first arc.

46. The tissue retractor of claim 45, wherein said

-61-

first arc subtends an angle of less than 180 degrees and said second arc subtends an angle of more than 180 degrees.

47. The tissue retractor of claim 46, wherein said first arc subtends an angle of about 90 degrees and said second arc subtends an angle of about 270 degrees.

48. The tissue retractor of claim 45, wherein said second arc subtends an angle that decreases along said length toward said working tip.

49. The tissue retractor of claim 48, wherein said second arc subtends an angle of about 200 degrees adjacent said first plate portion decreasing to an angle of less than 10 degrees adjacent said working tip.

50. The tissue retractor of claim 49, wherein said first arc subtends an angle of about 200 degrees.

51. The tissue retractor of claim 40, wherein said convex surface of said body is at a diameter that is greater than the diameter of the inner cylindrical surface of the cannula, said body being resiliently deformable to be insertable into the cannula with said convex surface in contact with the inner cylindrical surface of the cannula.

52. The tissue retractor of claim 40, further comprising an arm attached to said proximal first end of said body, said arm having a gripping surface to facilitate manipulation of said tissue retractor.

53. The tissue retractor of claim 52, wherein said arm is substantially perpendicular to said length of said body.

54. A tissue dilator, comprising:  
a sleeve having a tapered working end and an opposite

-62-

end, said working end configured to displace tissue; and  
a gripping portion on an outer surface of said sleeve  
adjacent said opposite end, said gripping portion defining a  
plurality of circumferential grooves configured for manually  
5 gripping the dilator to manipulate the dilator within  
tissue.

55. An apparatus for use in percutaneous surgery,  
comprising:

an elongated cannula having a length and defining a  
10 first area transverse to said length and an outer dimension  
sized for percutaneous introduction into a patient, said  
cannula further including a distal working end and an  
opposite proximal end, said cannula defining a working  
channel between said ends having a second area substantially  
15 equal to said first area and sized for receiving a surgical  
tool therethrough;

a viewing element connectable to a viewing apparatus and  
including a lens at a distal end thereof; and

a fixture supporting said viewing element relative to  
20 said cannula with said lens disposed adjacent said working  
end of said cannula.

56. The apparatus of claim 55 wherein said second area  
is sized to simultaneously receive a plurality of surgical  
tools therethrough.

25 57. The apparatus of claim 55, wherein said viewing  
element has a proximal end adjacent said proximal end of  
said cannula and includes an image transmission channel  
extending from said lens at least to said proximal end  
thereof.

30 58. The apparatus of claim 57, wherein said viewing  
element includes a fiber-optic cable having illumination



-63-

fibers and image transmission fibers disposed within said image transmission channel.

59. The apparatus of claim 55, wherein said fixture includes means for removably mounting said fixture to said cannula adjacent said proximal end of said cannula.

60. The apparatus of claim 59, wherein said fixture includes means for supporting said viewing element within said working channel.

61. The apparatus of claim 55, wherein said fixture includes:

a body having means for engaging said viewing element; and

means for clamping said body onto said cannula to support said fixture on said cannula.

62. The apparatus of claim 61, wherein said means for clamping includes:

a ring attached to said body, said ring sized to substantially encircle said cannula; and

means for compressing said ring about said cannula whereby said ring grips said cannula to support said fixture thereon.

63. The apparatus of claim 62, wherein said means for compressing said ring includes:

a pair of adjacent free ends;

a pair of opposing arms extending from a corresponding one of said free ends, said arms defining a slot therebetween and extending between said free ends; and

a mechanism connected to said arms and operable to compress said arms toward each other.

-64-

64. The apparatus of claim 63, wherein said mechanism includes:

- 5 a barrel cam disposed adjacent one of said pair of arms, said barrel cam having cam surface with at least one inclined ramp facing away from said one of said pair of arms;
- means for supporting said barrel cam relative to said pair of arms to permit translation of said barrel cam toward said pair of arms;
- 10 a lever arm including at least one projection facing said cam surface of barrel cam; and
- means for rotatably supporting said lever arm relative to said barrel cam with said at least one projection in substantially continuous contact with said cam surface of said barrel cam,
- 15 whereby rotation of said lever arm relative to said barrel cam causes said projection to slide along said ramp to push said barrel cam toward said pair of arms and said pair of arms together.

65. The apparatus of claim 64, wherein said mechanism further includes:

- 20 a threaded bore in one of said pair of arms distal from said barrel cam;
- bearing bores defined in the other of said pair of arms, said barrel cam and said lever arm, said bearing bores being aligned and coaxial with said threaded bore; and
- 25 a shoulder screw having a threaded shank for mating with said threaded bore, a non-threaded bearing shank extending through said bearing bores, and a head larger than said bearing bores for engaging said lever arm when said threaded shank is engaged within said threaded bore.
- 30

66. The apparatus of claim 65, wherein:  
said barrel cam has a surface opposite said inclined

-65-

ramp disposed adjacent said other of said arms; and  
said other of said arms includes a recess conforming to  
and receiving said surface of said barrel cam.

67. The apparatus of claim 64, wherein said cam surface  
5 of said barrel cam includes a recess at one end of said  
inclined ramp, said recess being sized to receive said  
projection of said lever arm therein.

68. The apparatus of claim 64, wherein said at least  
one inclined ramp is arcuate.

10 69. The apparatus of claim 68, wherein:  
said arcuate inclined ramp subtends an angle of about  
ninety degrees (90°),  
whereby said lever arm is rotated ninety degrees (90°)  
as the projection travels from one end of said ramp to the  
15 other.

70. The apparatus of claim 69, wherein said means for  
rotatably supporting said lever arm supports said lever arm  
to rotate through ninety degrees (90°) from a first position  
in which the lever arm is substantially parallel to said  
20 length of said cannula to a second position in which the  
elver arm is substantially perpendicular to said length of  
said cannula.

71. The apparatus of claim 64, wherein:  
said cam surface of said barrel cam includes two  
25 inclined ramps; and  
said lever arm includes two projections in contact with  
a corresponding one of said inclined ramps.

72. The apparatus of claim 64, wherein said at least  
one projection includes a rounded tip for sliding contact  
30 with said at least one inclined ramp.

-66-

73. The apparatus of claim 63, wherein said means for compressing said ring further includes a slot defined in said body contiguous with said slot defined between said free ends of said ring.

5        74. The apparatus of claim 57, wherein:  
      said viewing element includes an optics cannula carrying  
      said image transmission channel and having an  
      irrigation/aspiration channel extending therethrough; and  
      said body of said fixture defines an  
10        irrigation/aspiration port in communication with said  
      irrigation/aspiration channel when said viewing element is  
      supported by said fixture, said port being connectable to a  
      source of irrigation fluid or aspiration vacuum.

      75. The apparatus of claim 55, wherein:  
15        said viewing element includes an optics cannula having a  
      proximal end fixed to said fixture and a distal end  
      supporting said lens; and  
      said fixture includes a ring slidably mounted for  
      translation along and rotation about said cannula, whereby  
20        the position of said lens relative to said distal end of  
      said cannula can be varied by movement of said ring relative  
      to said cannula.

      76. The apparatus of claim 75, wherein said optics  
      cannula has a length greater than said length of said  
25        elongated cannula.

      77. The apparatus of claim 75, wherein said optics  
      cannula supports said lens has an optical axis oriented at  
      an angle relative to a longitudinal axis of said optics  
      cannula.

-67-

78. The apparatus of claim 77, wherein said optics cannula is fixed to said fixture so that said optical axis is angled toward said working channel of said cannula.

5 79. The apparatus of claim 55, wherein said cannula is cylindrical and said first area is area is circular.

80. A fixture for supporting a viewing element within a cannula defining a working channel, comprising:

a body defining an optics bore for supporting a portion of the viewing element;

10 a ring attached to said body, said ring sized to substantially encircle the cannula; and

means for compressing said ring about the cannula whereby said ring grips the cannula to support said fixture thereon.

15 81. The fixture according to claim 80, wherein: said body includes a support column extending between said body and said ring and configured to reside outside the cannula; and

20 said body is configured so that said optics bore is aligned with a portion of the working channel of the cannula when said fixture is supported on the cannula.

82. The fixture of claim 80, wherein said means for compressing said ring includes:

a pair of adjacent free ends;

25 a pair of opposing arms extending from a corresponding one of said free ends, said arms defining a slot therebetween and extending between said free ends; and

a mechanism connected to said arms and operable to compress said arms toward each other.

-68-

83. The fixture of claim 82, wherein said mechanism includes:

5 a barrel cam disposed adjacent one of said pair of arms, said barrel cam having cam surface with at least one inclined ramp facing away from said one of said pair of arms; means for supporting said barrel cam relative to said pair of arms to permit translation of said barrel cam toward said pair of arms;

10 a lever arm including at least one projection facing said cam surface of barrel cam; and

means for rotatably supporting said lever arm relative to said barrel cam with said at least one projection in substantially continuous contact with said cam surface of said barrel cam,

15 whereby rotation of said lever arm relative to said barrel cam causes said projection to slide along said ramp to push said barrel cam toward said pair of arms and said pair of arms together.

84. The fixture of claim 83, wherein said mechanism further includes:

20 a threaded bore in one of said pair of arms distal from said barrel cam;

bearing bores defined in the other of said pair of arms, said barrel cam and said lever arm, said bearing bores being aligned and coaxial with said threaded bore; and

25 a shoulder screw having a threaded shank for mating with said threaded bore, a non-threaded bearing shank extending through said bearing bores, and a head larger than said bearing bores for engaging said lever arm when said threaded shank is engaged within said threaded bore.

30

85. The fixture of claim 84, wherein:

said barrel cam has a surface opposite said inclined

-69-

ramp disposed adjacent said other of said arms; and  
said other of said arms includes a recess conforming to  
and receiving said surface of said barrel cam.

86. The fixture of claim 83, wherein said cam surface  
5 of said barrel cam includes a recess at one end of said  
inclined ramp, said recess being sized to receive said  
projection of said lever arm therein.

87. The fixture of claim 83, wherein said at least one  
inclined ramp is arcuate.

10 88. The fixture of claim 87, wherein:  
said arcuate inclined ramp subtends an angle of about  
ninety degrees (90°),  
whereby said lever arm is rotated ninety degrees (90°)  
as the projection travels from one end of said ramp to the  
15 other.

89. The fixture of claim 88, wherein said means for  
rotatably supporting said lever arm supports said lever arm  
to rotate through ninety degrees (90°) from a first position  
in which the lever arm is substantially parallel to said  
20 length of said cannula to a second position in which the  
elver arm is substantially perpendicular to said length of  
said cannula.

90. The fixture of claim 83, wherein:  
said cam surface of said barrel cam includes two  
25 inclined ramps; and  
said lever arm includes two projections in contact with  
a corresponding one of said inclined ramps.

91. The fixture of claim 83, wherein said at least one  
projection includes a rounded tip for sliding contact with  
30 said at least one inclined ramp.

-70-

92. The fixture of claim 82, wherein said means for compressing said ring further includes a slot defined in said body contiguous with said slot defined between said free ends of said ring.

5 93. An apparatus for supporting a viewing element for percutaneous surgery on the spine comprising:  
an elongated cannula having a length along a longitudinal axis from a distal working end to an opposite proximal end, a first portion of said length being sized for  
10 introduction into the patient adjacent the spine and having a length less than the distance from the lamina of a spinal vertebra to the skin of the patient, and a second portion of said length external to the patient and being about  
one-fourth (1/4) of the length of said first portion; and  
15 a fixture supporting the viewing element and having means for mounting said fixture on said cannula at said second portion of said cannula.

94. An apparatus for use in percutaneous surgery on the spine comprising:  
20 an elongated cannula having a length along a longitudinal axis from a distal working end to an opposite proximal end, a first portion of said length being sized for introduction into the patient adjacent the spine and having  
a length less than the distance from the lamina of a spinal  
25 vertebra to the skin of the patient, and a second portion of said length external to the patient and being about one-fourth (1/4) of the length of said first portion.

95. An apparatus for use in percutaneous surgery on the spine comprising:  
30 an elongated cannula having a length along a longitudinal axis from a distal working end to an opposite



-71-

proximal end, a portion of said length being sized for introduction into the patient adjacent the spine, said cannula having a transverse dimension in a plane perpendicular to said longitudinal axis, said transverse dimension being substantially constant along at least the length of said portion, wherein said length of said cannula is between 5.5-7.0 times greater than said transverse dimension.

96. An apparatus for use in percutaneous surgery, comprising:

an elongated device for defining a working channel at a surgical site, said elongated device having an outer surface defining an outer dimension;

a viewing element connectable to a viewing apparatus and including a lens at a distal end thereof; and

a fixture supporting said viewing element relative to said elongated device with said lens disposed adjacent said working channel defined by said elongated device.

97. The apparatus of claim 96, wherein said fixture includes means for removably mounting said fixture to said outer surface of said elongated device.

98. An apparatus for use in percutaneous surgery comprising:

an elongated tissue retractor having a working tip configured to atraumatically displace tissue and a plate having a width sufficient to retract tissue from a surgical site; and

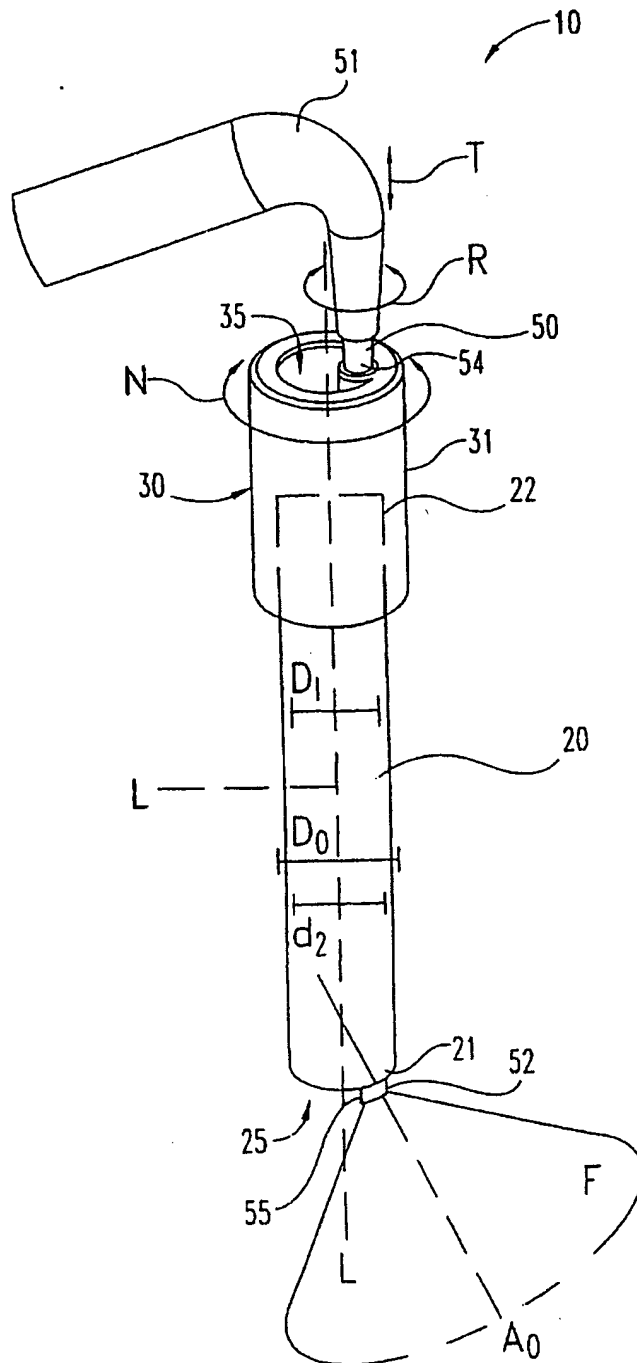
a viewing element connected to said retractor, said viewing element having a lens adjacent said working tip of said retractor.

99. The apparatus according to claim 98, further

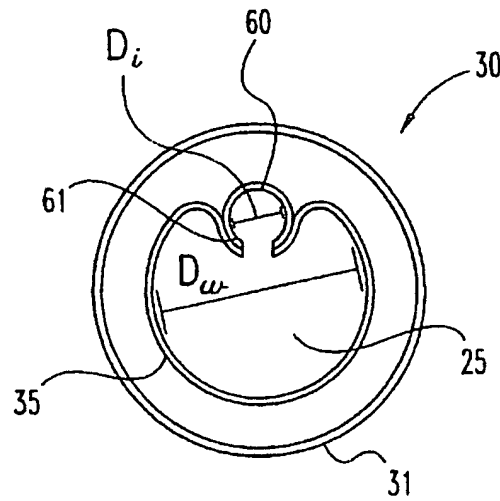
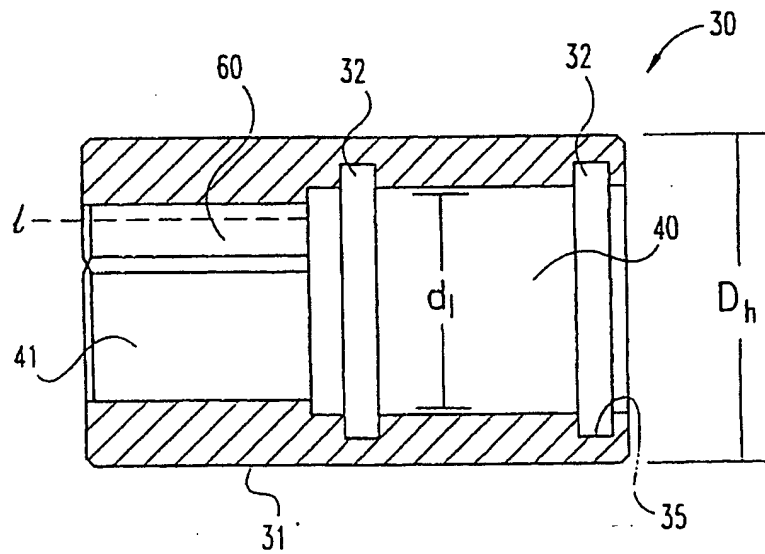
-72-

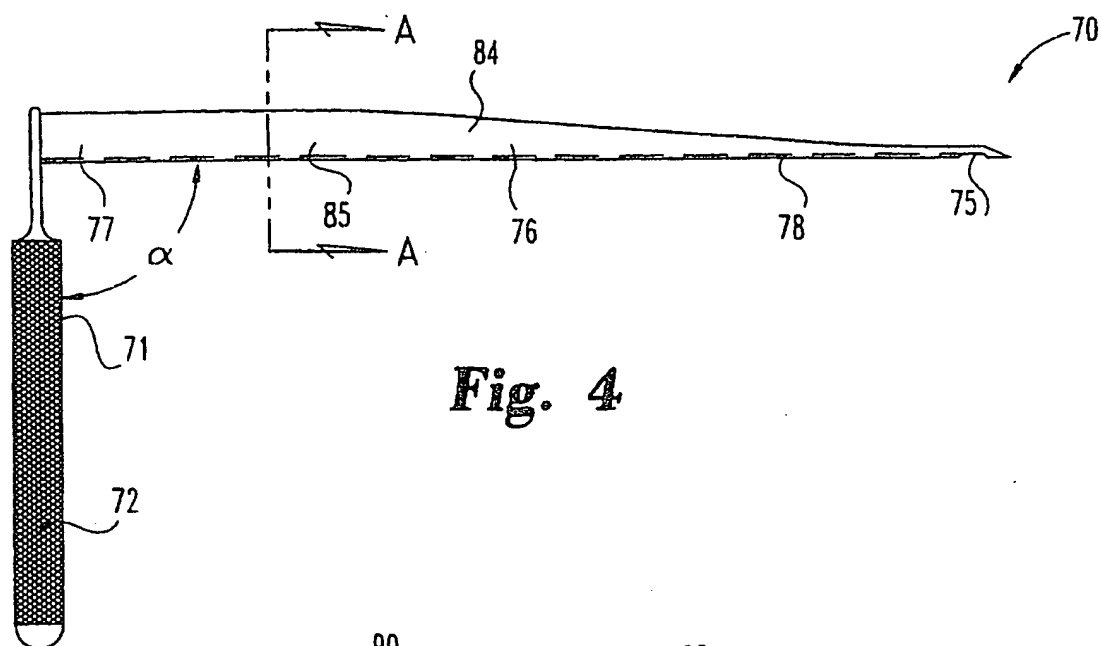
comprising means for movably connecting said viewing element to said retractor.

5 100. The apparatus according to claim 99, wherein said means for movably connecting includes at least one clip attached to said plate of said retractor, said clip configured to retain a portion of said viewing element therein.

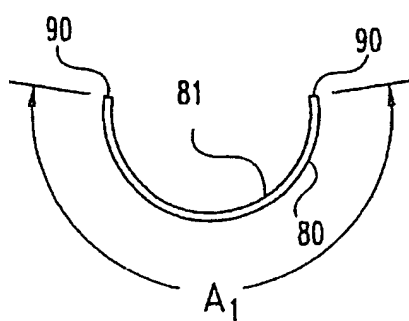


**Fig. 1**

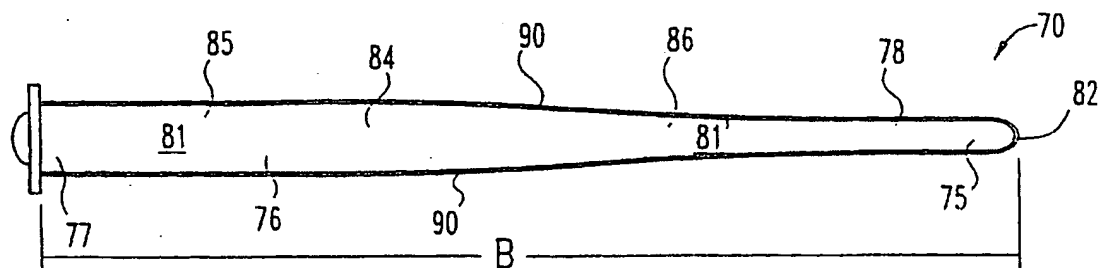
**Fig. 2****Fig. 3**



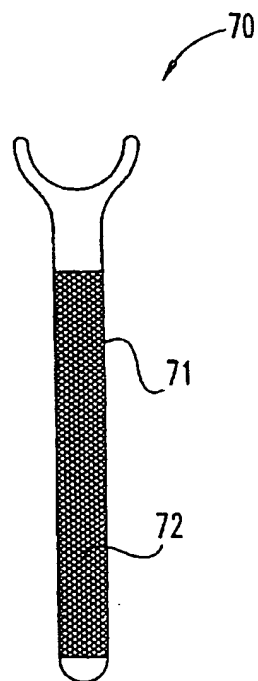
**Fig. 4**



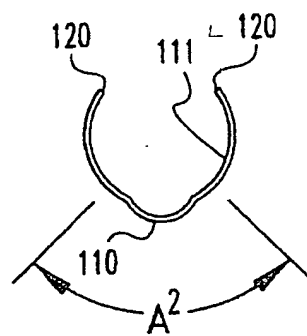
**Fig. 4A**



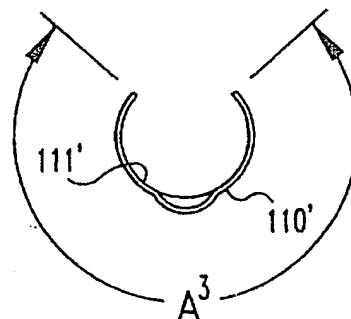
**Fig. 5**



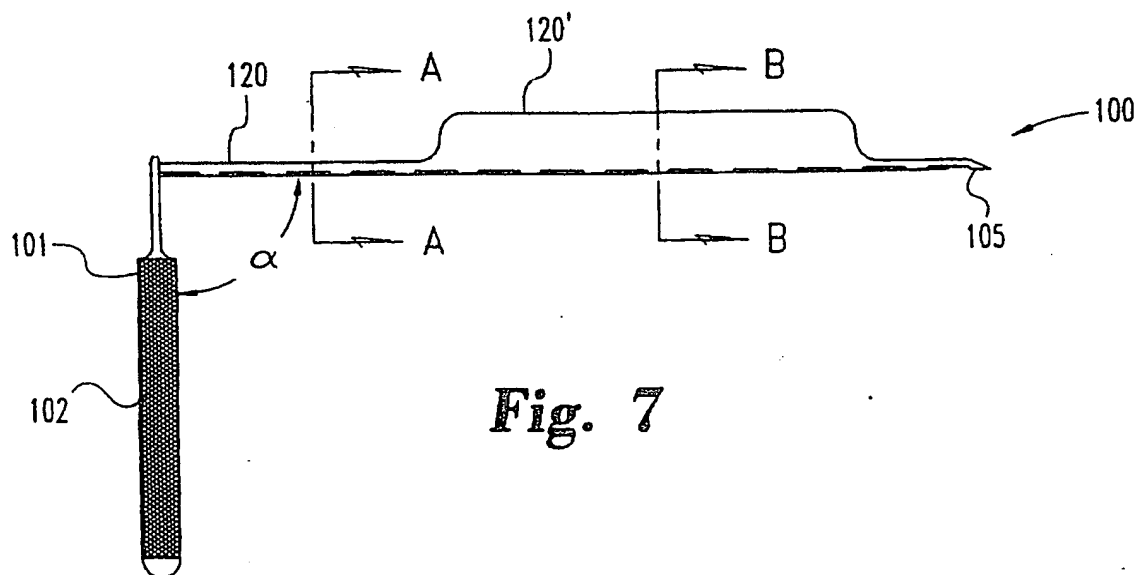
**Fig. 6**



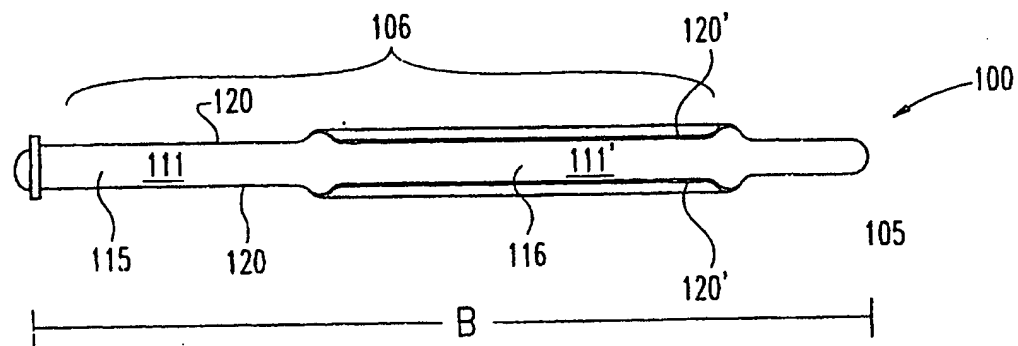
**Fig. 7A**



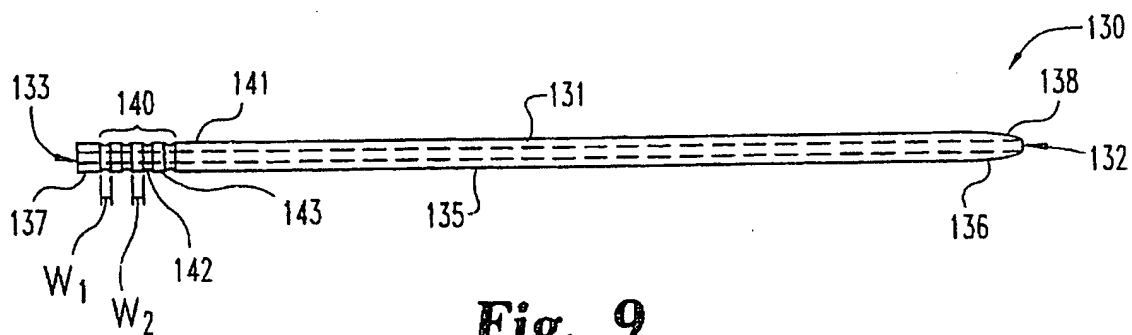
**Fig. 7B**



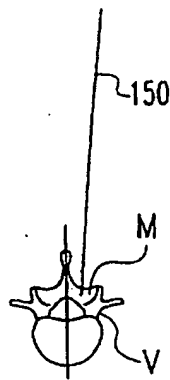
**Fig. 7**



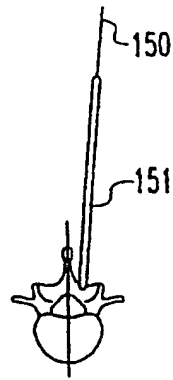
**Fig. 8**



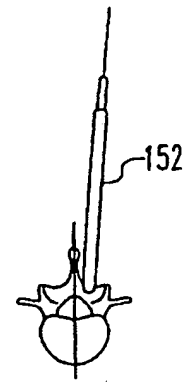
**Fig. 9**



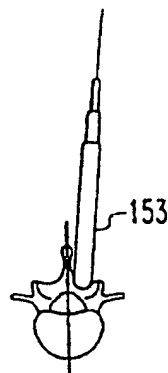
**Fig. 10a**



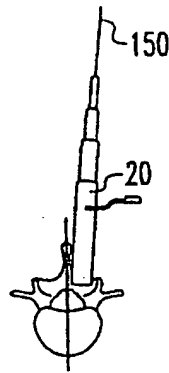
**Fig. 10b**



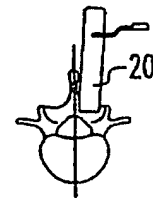
**Fig. 10c**



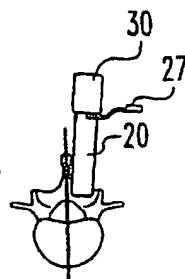
**Fig. 10d**



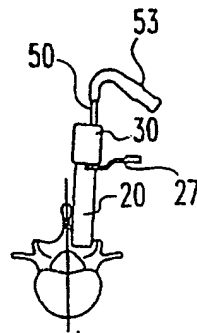
**Fig. 10e**



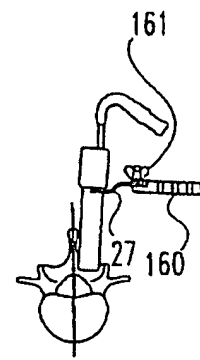
**Fig. 10f**



**Fig. 10g**

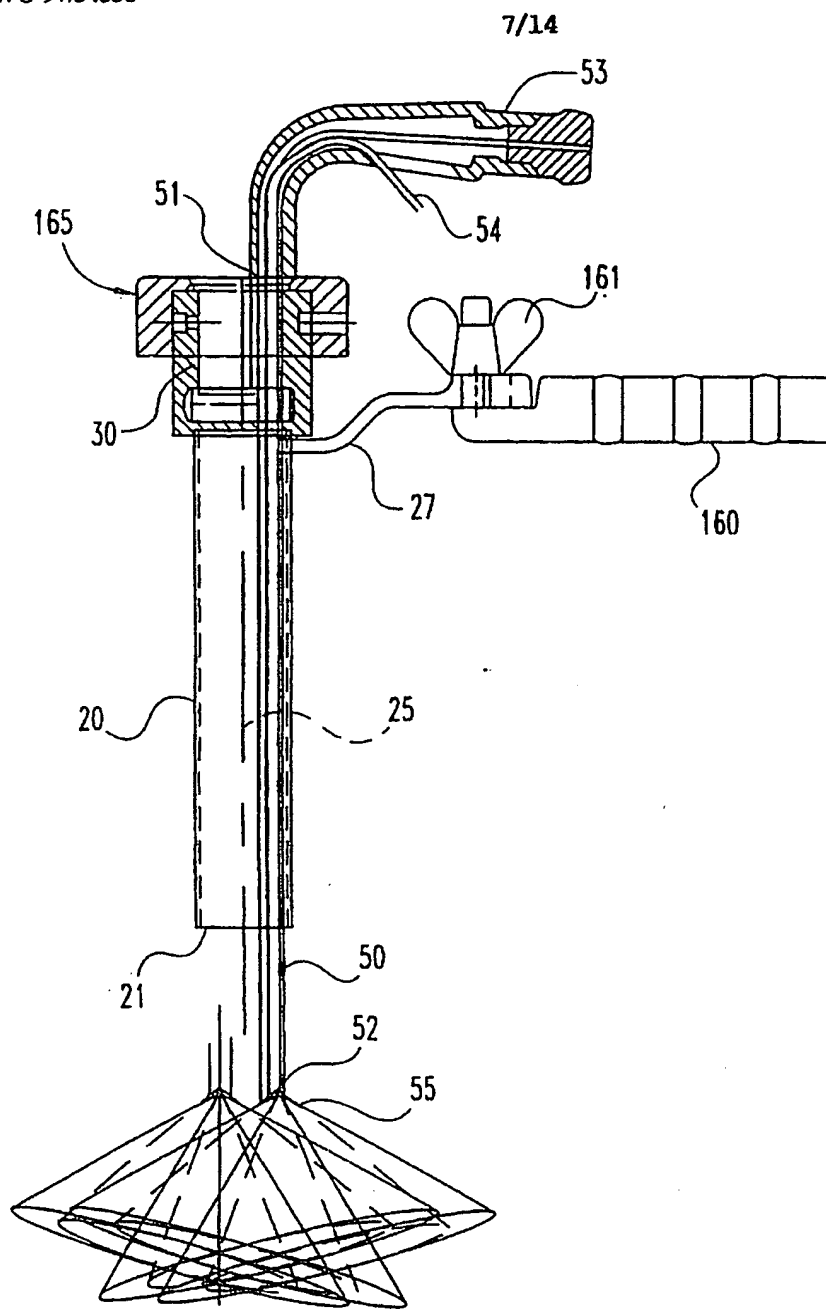


**Fig. 10h**

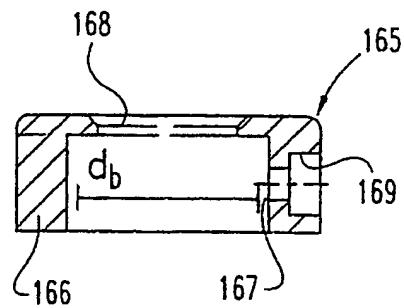


**Fig. 10i**

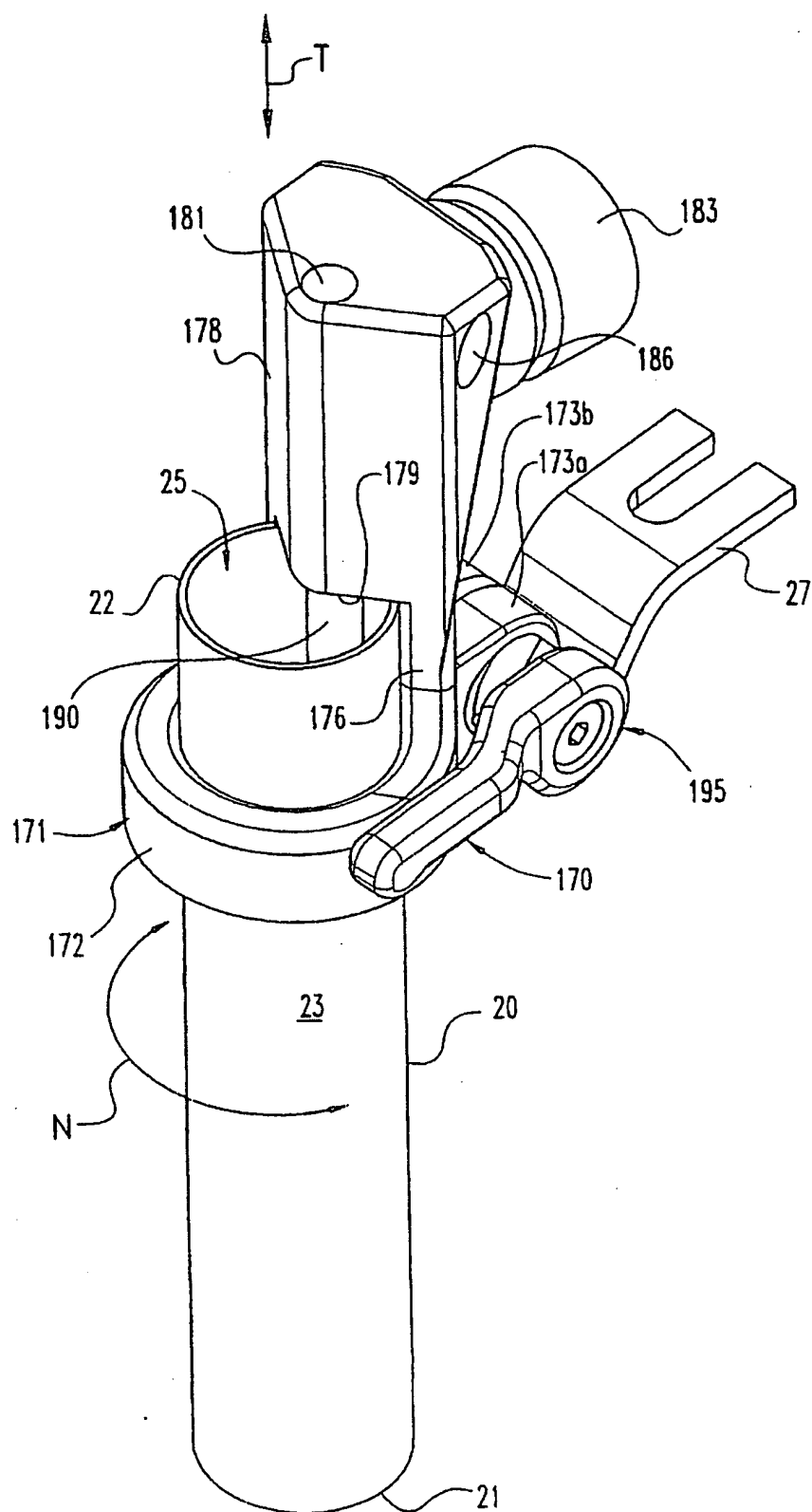




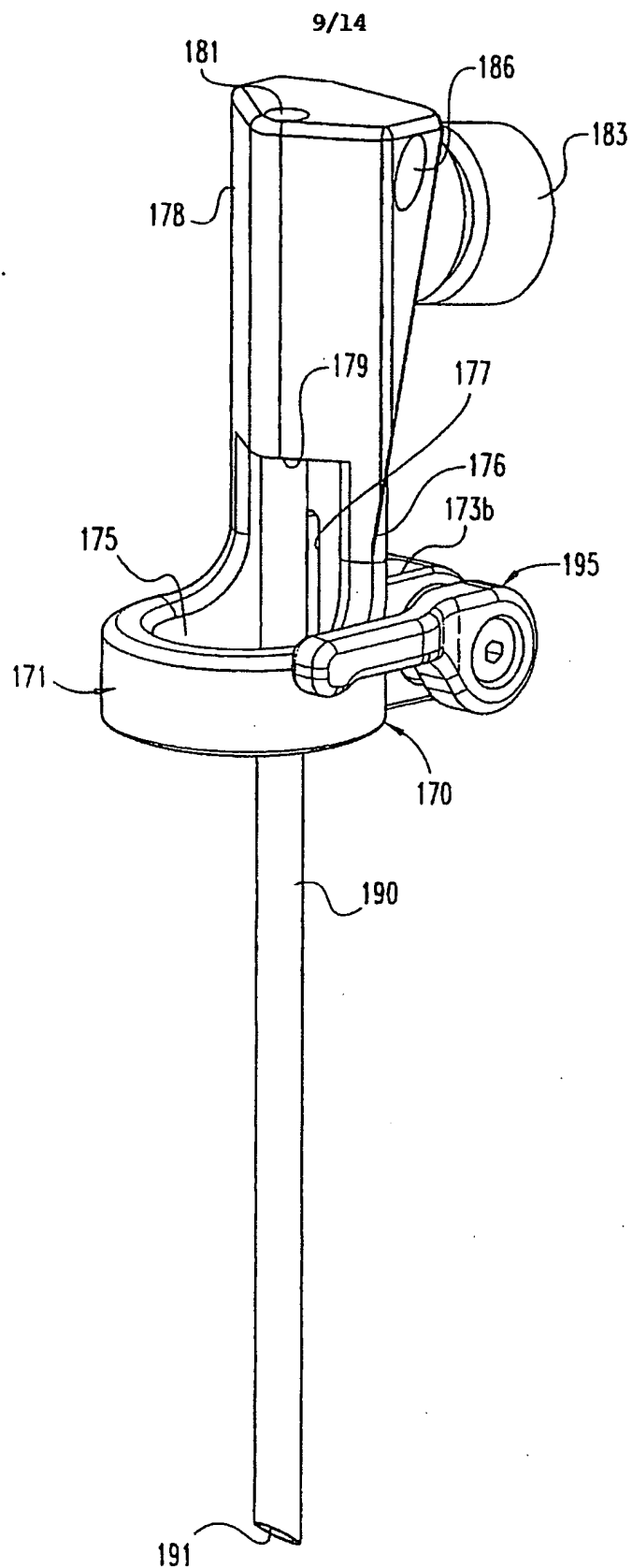
**Fig. 11**

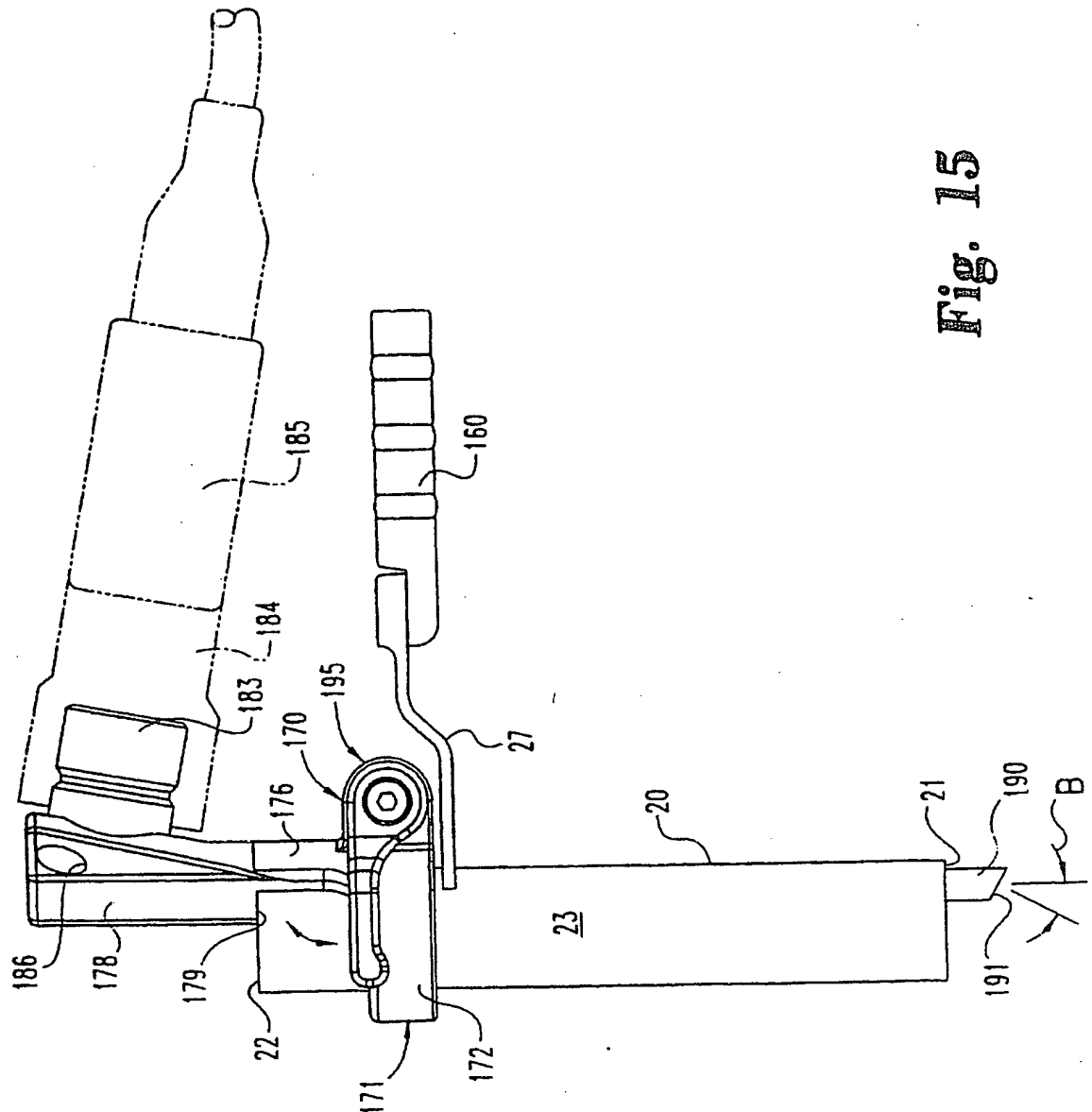


**Fig. 12**

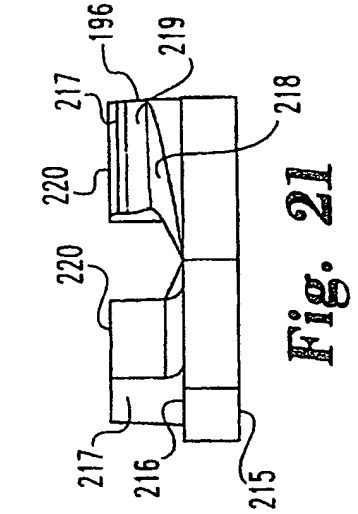
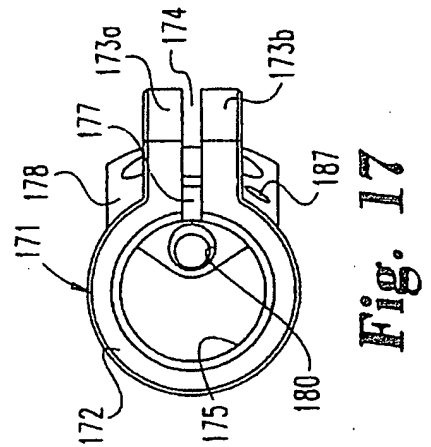
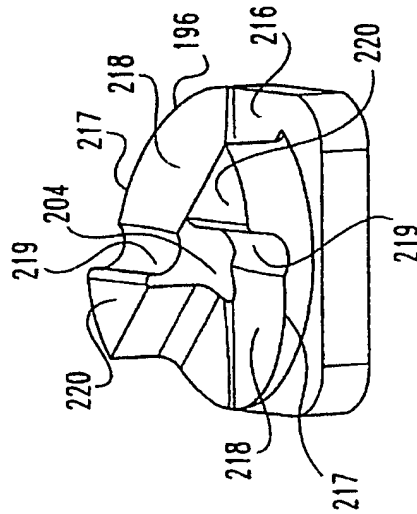
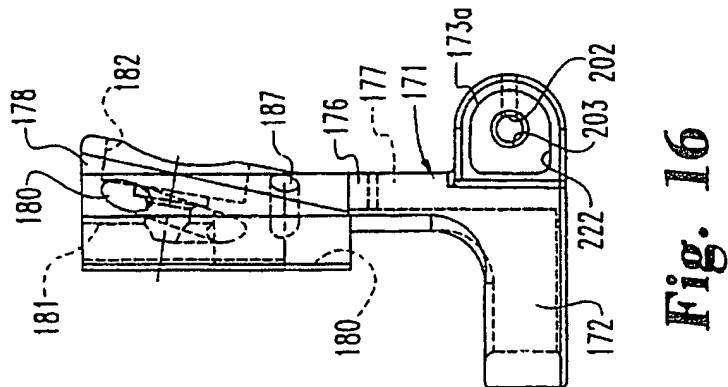
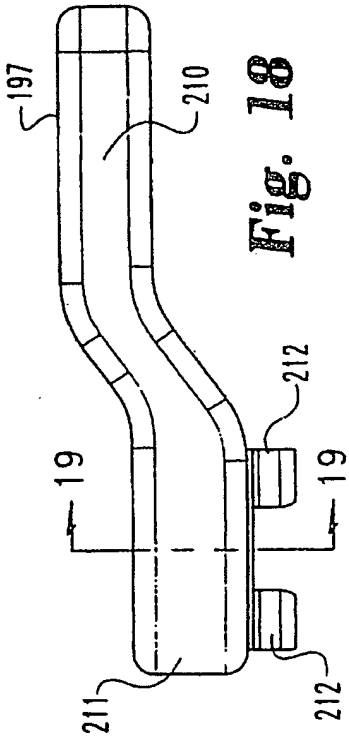
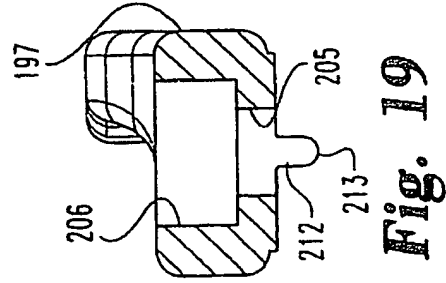


**Fig. 13**

**Fig. 14**



15  
1  
10  
1



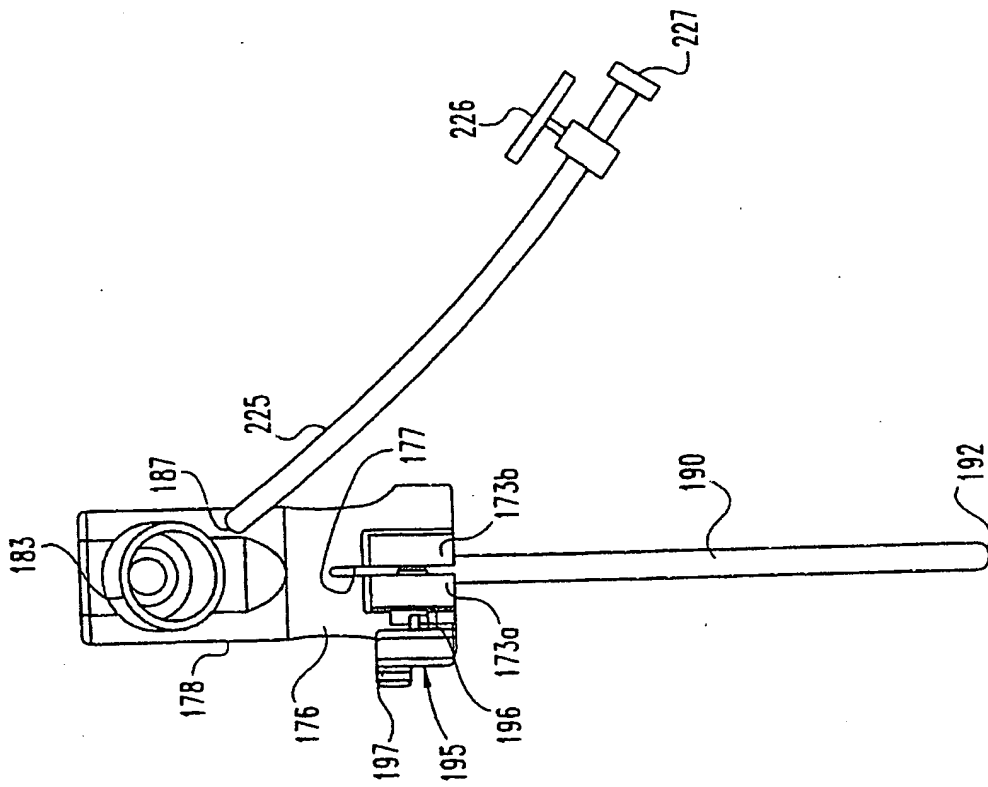


Fig. 22

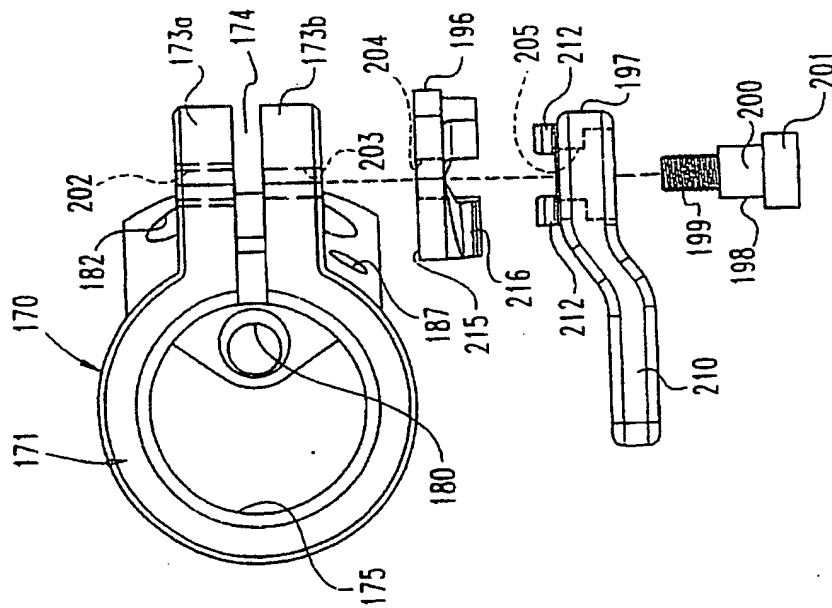


Fig. 23

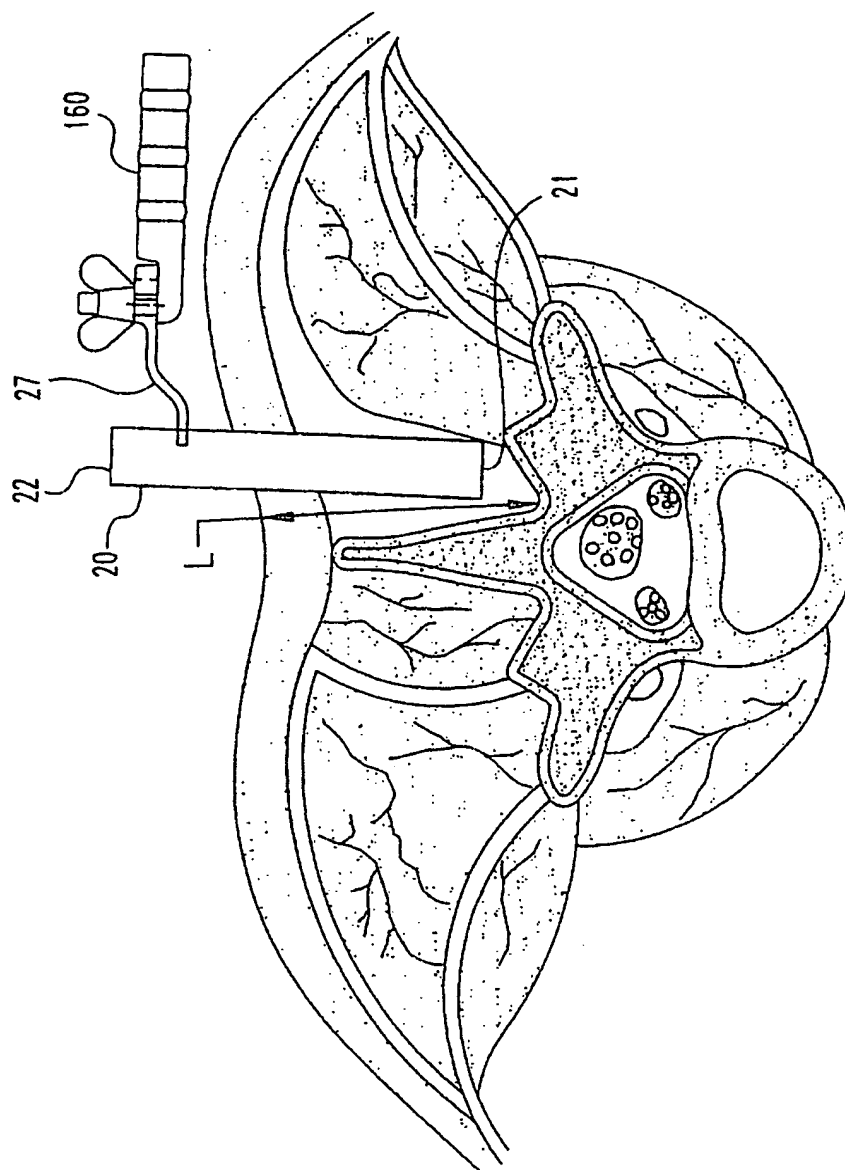


Fig. 24

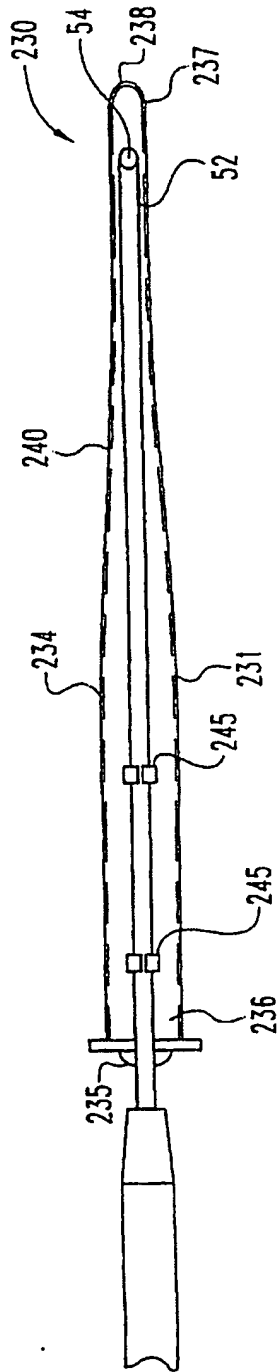


Fig. 26

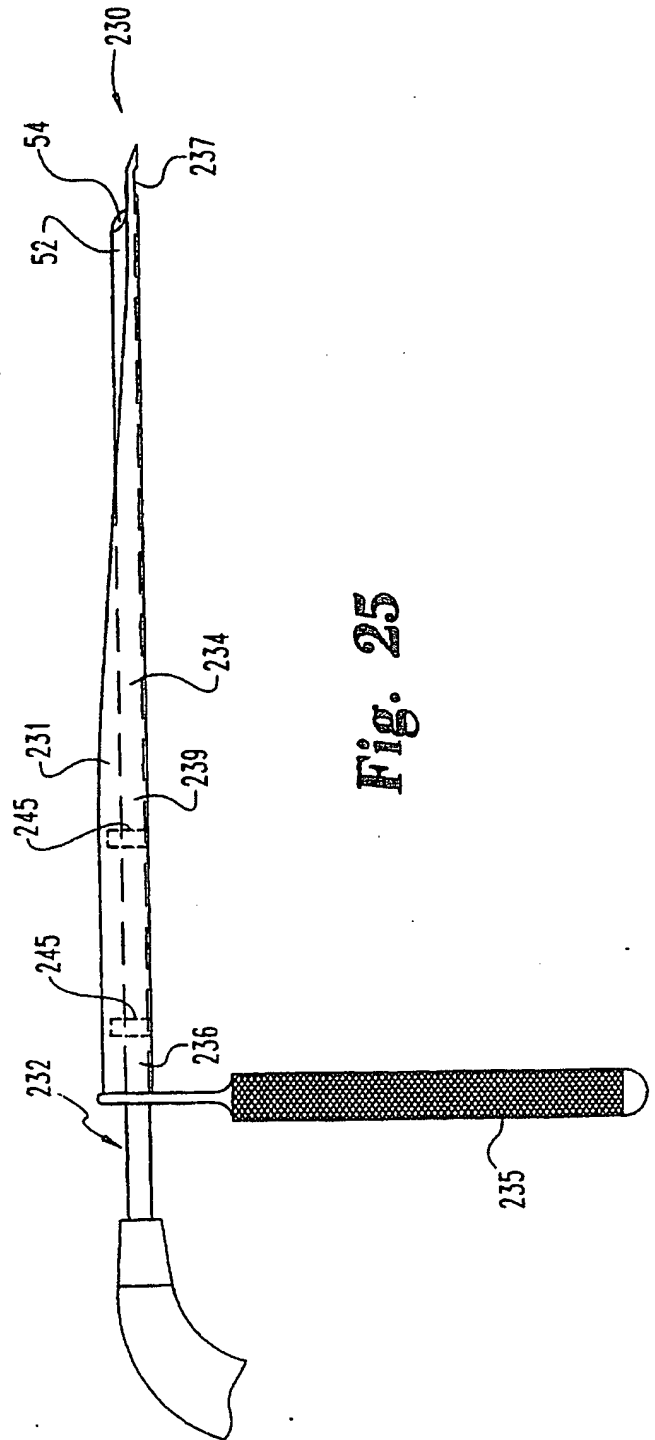


Fig. 25



# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 97/04004

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61B17/34 A61M29/00 A61B17/02

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 92 19146 A (WILD ANDREW MICHAEL) 12 November 1992  see page 14, paragraph 2 see page 15, paragraph 3 - page 18, paragraph 2  ---	1,8,21, 32,80, 93,96,97
X	DE 39 36 811 A (STORZ KARL) 27 September 1990	1,8,21, 32,93, 96,97
A	see column 2, line 40 - line 61  ---  -/--	80

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

- \* "A" document defining the general state of the art which is not considered to be of particular relevance
- \* "E" earlier document but published on or after the international filing date
- \* "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \* "O" document referring to an oral disclosure, use, exhibition or other means
- \* "P" document published prior to the international filing date but later than the priority date claimed

- \* "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \* "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \* "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- \* "&" document member of the same patent family

Date of the actual completion of the international search

16 September 1997

Date of mailing of the international search report

26.09.97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
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Fax (+ 31-70) 340-3016

Authorized officer

Gérard, B

# INTERNATIONAL SEARCH REPORT

Intern. Appl. Application No

PCT/US 97/04004

## C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 93 14801 A (WILK PETER J) 5 August 1993  see page 7, paragraph 4 - page 8, paragraph 1; figure 3 ---	1-6, 8-12, 14-18, 20-24, 32-35, 93,96,97
Y	WO 93 15647 A (LINVATEC CORP) 19 August 1993  see figures 3,17 ---	1-6, 8-12, 14-18, 20-24, 32-35, 93,96,97
A	WO 95 22285 A (SMITH & NEPHEW RICHARDS INC) 24 August 1995 see figures 19,20 ---	1
X	US 4 498 902 A (ASH STEPHEN R ET AL) 12 February 1985 see column 3, line 11 - line 15 ---	40,42-44
X	US 4 545 374 A (JACOBSON ROBERT E) 8 October 1985 see column 8, line 53 - column 9, line 3 ---	40-42, 52,53
A	US 4 899 729 A (GILL STEVEN S ET AL) 13 February 1990 see page 5, line 49 - line 51 see column 6, line 30 - line 33 ---	51
X	US 5 472 426 A (BONATI ALFRED O ET AL) 5 December 1995 see column 5, line 29 - line 37 see column 8, line 44 - line 46; figure 3 ---	54,98,99
A	EP 0 303 824 A (ESPEJO MARTINEZ ANTONIO ;CASTROVIEJO GARCIA EDUARDO (ES)) 22 February 1989 see column 4, line 7 - line 12 ---	54
X	FR 2 714 285 A (IMPACT ;INST ABORDAJES PERCUTANEOS) 30 June 1995 see page 4, line 24 - line 29 ---	94,95
X	DE 15 66 116 A (MEDICAL PRODUCTS CORP.) 8 January 1970 see page 19; figure 1 -----	98-100

INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 97/04004

**Box I** Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II** Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 97/ 04004

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

SUBJECT 1: claims 1-39,55-93,96,97 holding a viewing element in a cannula  
 SUBJECT 2: claims 40-53, 98-100 blunt trip retractor  
 SUBJECT 3: claim 54 dilator  
 SUBJECT 4: claims 94 and 95 cannula with specified longitudinal dimensions

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/04004

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9219146 A	12-11-92	NONE	
DE 3936811 A	27-09-90	NONE	
WO 9314801 A	05-08-93	US 5183471 A US 5269772 A AU 3586893 A	02-02-93 14-12-93 01-09-93
WO 9315647 A	19-08-93	US 5341240 A AU 3480893 A US 5416638 A US 5519532 A	23-08-94 03-09-93 16-05-95 21-05-96
WO 9522285 A	24-08-95	AU 1847195 A	04-09-95
US 4498902 A	12-02-85	NONE	
US 4545374 A	08-10-85	NONE	
US 4899729 A	13-02-90	EP 0206553 A JP 62016772 A	30-12-86 24-01-87
US 5472426 A	05-12-95	US 5269797 A AU 663338 B AU 2659892 A CA 2118811 A EP 0603313 A JP 7502419 T WO 9304652 A	14-12-93 05-10-95 05-04-93 18-03-93 29-06-94 16-03-95 18-03-93
EP 0303824 A	22-02-89	AU 1972888 A JP 1119242 A US 4919653 A	02-02-89 11-05-89 24-04-90
FR 2714285 A	30-06-95	NONE	
DE 1566116 A	08-01-70	NONE	

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